COMM	HTTEE/PANEL INFO.		
	Advisory Committee Information Line	1	4/19/95
COMP	LIANCE POLICY GUIDES		
	Medical Device GMP Guidance for FDA Investigators FDA84-4191	59	4/ 1/87
	Status and Responsibilities of Contract Sterilizers Engaged in the Sterilization of Drugs and Devices CPG 7150.16	3	3/ 1/84
039	CPG 7124.21 - Condom; Defect - Criteria for Direct Reference Seizure	6	12/30/8
040	CPG 7132a.15 - Computerized Drug Processing; Source Code for Process Control Application Programs	2	4/16/87
041	CPG 7150.10 Chapter 50 - General Policy Guide - Health Fraud - Factors in Considering Regulatory Action	5	6/ 3/87
042	Oxygen Equipment - Emergency and OTC Use CPG 7124.10	1	9/24/87
043	CPG 7132a.16 - Compressed Medical Gases - Direct Reference Authority for Sending Regulatory Letters for Specific CGMP Deviations	3	11/5/87
044	Blood Pressure Measurement Devices (Sphygmomanometers) - Accuracy CPG 7124.23	3	9/ 8/88
045	Status of Dental Supplies such as Denture Cleaners, Adhesives, Cushions, and Repair Materials as a Device or Cosmetic CPG 7124.05	1	8/ 9/88
	Electrical Muscle Stimulators (EMS) :CPG 7124.26	2	11/21/8
	CPG 7150.01; Certification of Free Sales	2	6/ 1/87
	Reuse of Medical Disposable Devices: CPG 7124.16	2	9/24/87
049	\mathbf{J}	3	10/19/9
050	[510(k)] or an Approved Premarket Approval Application (PMA) CPG 7124.30	3	2/26/91
	CPG 7382.004 - Field Compliance Testing of Cabinet X-Ray Equipment	26	10/20/8
	CPG 7348.809 - Institutional Review Board	53	6/ 6/89
	CPG 7348.808 - Good Laboratory Practice (Nonclinical Laboratories)	32	6/ 6/89
060		32	9/ 1/91
062	CPG 7151.02 FDA Access to Results of Quality Assurance Program Audits and Inspections CPG 7382.830A - Sterilization of Medical Devices	1 65	1/ 3/96 10/ 1/89
	CPG 7382.830B - Contract Sterilizers	48	10/ 1/89
	CPG 7382.010 - Medical Device Problem Reporting	20	10/ 1/89
	CPG 7382.011 - Enforcement of the Medical Device Reporting (MDR) Regulation	27	1/ 1/92
073	CPG 7348.810 - Sponsors, Contract Research Organizations and Monitors	25	12/31/9
075		5	5/15/90
195	CPG 7150.01, Certification for Exports	8	8/15/94
204	Procedures for Obtaining FDA Approval to Export Unapproved Medical Devices	32	1/13/95
493	CPG 7150.09 Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities	5	7/ 1/91
534	CPG 7382.008 - Monitoring Devices of Foreign Origin - Imports	12	10/ 1/91
825	CPG 7383.003 510(K) Premarket Approval Inspections	23	3/15/93
	LIANCE\LETTERS		
	Device Industry Letter: Enforcement Activities/Policy/Discussion of the Reference List	7	1/21/93
961	Letter: Re-Use of Single-Use or Disposable Medical Devices	3	12/27/9

	DSMA Facts Domain		
		PAGES	DATE
	LIANCE\OTHER		
	Draft Instructions for Medical Device Listing	11	7/17/95
	Medical Device Establishment Registration Information and Instructions	11	5/ 1/87
	FDA Regulatory Procedures Manual Chapter 8-10 Warning Letters	19	5/23/91
293	Condoms: Inspection and Sampling at Domestic Manufacturers and of all Repackers; Sampling from all Importers	14	4/ 8/87
492	Points to Consider for Internal Reviews and Corrective Action Operating Plans	11	6/ 1/91
508	A Pocket Guide to Device GMP Inspections - Inspections of Medical Device Manufacturers and GMI Regulation	P 26	11/ 1/91
586	Regulatory Procedures Manual Chapter 9-87 - Priority Enforcement Strategy for Problem Importers	10	1/28/92
796	Inspections of Foreign Device Manufacturers	9	7/ 1/94
868	Compressed Medical Gases Guideline	30	2/ 1/89
874	Kit Certification and Information for Kit 510(k)s	2	6/ 7/93
918	Guideline for the Manufacturer of In Vitro Diagnostic Products	33	1/10/94
977	A Guide for the Submission of Abbreviated Radiation Safety Reports on Cephalometric Devices	8	3/ 1/96
978	A Guide for the Submission of An Abbreviated Radiation Safety Report on X-ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use	7	3/ 1/96
979	A Guide for the Submission of Abbreviated Radiation Safety Reports on Image Receptor Support Devices for Mammographic X-ray Systems	6	3/ 1/96
COMP	LIANCE\PROGRAMS		
	CPG7382.830 Inspection Med/Dev. Manuf.	50	5/ 1/95
	CPG7382.830 Attach. A, GMP Inspections (unchanged)	39	5/ 1/95
	CPG7382.830, Attachment A-1, Process for Compliance Review of Class I & II 510(k)	38	5/ 1/95
7702	Submissions/PMA SupplementsSubmission Review	30	3/ 1/73
5702	CPG 7382.830 Atts B, C, D, E, & F	75	5/ 1/95
	CPG 7382.830 Att G, Model Warning letter	32	5/ 1/95
	CPG7382.830 April 7, 1995 Letter	4	5/10/95
	Additional FDA Recommendations to the GMP Advisory Committee	2	9/15/95
COMP	LIANCE\TRACKING		
875	Device Tracking Questions and Answers Based on the Final Rule	21	8/26/93
DEVIC	E CATEGORIES		
017	Classifying Your Medical Devices FDA87-4223	7	1/ 1/87
	WORKSHOP SCHEDULE	4	0/10/07
	DSMA Workshop Schedule FY'96	1	3/12/96
258	Prospective Third Party Information Session Registration Information	3	4/ 3/96
	UCTIONS & INDEXES	1	1/20/06
	Facts-On-Demand Instruction Page	1	4/30/96
299	How to Order Publications (from non-DSMA sources)	1	9/25/91
	DSMADOC.ALL, sorted by Title	55	5/11/96
	Division of Small Manufacturers Assistance Publication Order Form (DSMA Order Form)	3	3/15/96
4913	DSMADOC.ONE, sorted by Shelf_#	52	5/11/96

		IAGES	DATE
5913	DSMADOC.DAT, sorted by DocDate	55	5/11/96
	DSMADOC.LOG, sorted by Login_Date	52	5/11/96
	Access to Complete DSMA Facts index from WWW	1	3/11/96
	DSMA Facts Category Index	1	6/ 5/96
	Center & Office Director Letters	2	3/21/96
	Committe/Panel Info.	1	3/21/96
	Compliance\Letters	1	3/21/96
	Compliance\Policy Guides	1	3/21/96
	Compliance\Programs	1	3/21/96
	Compliance\Other	1	3/21/96
	Compliance\Tracking	1	3/21/96
	Instructions & Indexes	2	3/21/96
	Manufacturer Assistance\General	1	3/21/96
	MDR Policies\Guidelines	1	3/21/96
	Medwatch Information	2	3/21/96
	ODE\Blue Book	2	3/21/96
	ODE\DCLD\ GUIDANCE	1	3/21/96
	ODE\DCRND\ GUIDANCE	2	3/21/96
	ODE\DGRD\ GUIDANCE	2	3/21/96
	ODE\DOD\ GUIDANCE	1	3/21/96
	ODE\DRAERD\ GUIDANCE	2	3/21/96
	ODE\OTHER\ GUIDANCE	2	3/21/96
	POSTMARKET SURVEILLANCE\OTHER	1	3/21/96
	RADIOLOGICAL HEALTH - LASERS	1	3/21/96
	RADIOLOGICAL HEALTH - MICROWAVE	1	3/21/96
	RADIOLOGICAL HEALTH - NON-IONIZING	1	3/21/96
	RADIOLOGICAL HEALTH - OTHER	1	3/21/96
	RADIOLOGICAL HEALTH - SUNLAMPS	1	3/21/96
	RADIOLOGICAL HEALTH - TELEVISION	1	3/21/96
	RADIOLOGICAL HEALTH - ULTRASONIC	1	3/21/96
	PUBLIC INFORMATION\OTHER	1	3/21/96
	REGULATIONS\CFR PARTS	1	3/21/96
	REGULATIONS\OTHER	1	3/21/96
	REGULATIONS\FOREIGN	1	3/21/96
	REGULATIONS\UNCODIFIED	1	3/21/96
	SAFETY ALERTS	1	3/21/96
	WORKSHOPS	2	3/21/96
	DSMA Facts Index (CDRH Facts-on-Demand)	1	4/26/96
LETTE	RS\CENTER & OFFICE DIRECTOR		
	Letter - Condom Manufacturers and Distributors: Re: Air Burst Test on Condom Products	2	4/ 5/94
170	Citizen's Petition, Docket No. 95P-0110, Response by William B Schultz	13	11/17/9
	Revised Medical Device reporting (MDR) Letter	2	5/31/96
457	Radiation Exposure From Medical Imaging Demonstrations: To Manufacturers of Imaging Devices,	10	4/16/90
	Officials for Major Medical Meetings, Professional Medical Organizations		
589	Denter Handpiece Sterilization Letter-	1	9/28/92
601	Burlington Letter: President/CEO - Progress in the Premarket Review Program	14	11/1/95

	DSMA Facts Domain		
		<u>PAGES</u>	DATE
639	Memorandum Electromagnetic Compatibility for Medical Devices: Issues and Solutions	2	6/13/95
	Letter to President/CEO from Burlington on Status of 510(k) Submissions	7	5/18/95
LETTE	RS\OTHER		
	Letter - To All Manufacturers of Latex Devices	2	5/ 1/91
522	Letter - Recodification of the Radiation Control for Health and Safety Act - To All Manfacturers and	2	6/12/91
	Importers of Electronic Products, Trade Associations, Radiological Health Personnel		- 4 - 10 -
	Letter - Endoscopy and Laparoscopy Accessories - To Medical Device Industry	2	5/17/93
552	Letter - Second Tracking Regulation Transmittal Letter and Proposed List of Devices Subject to	2	6/ 8/92
585	Tracking Compliance Safe Medical Devices Act Letter	6	1/17/92
303	Compitance sale inedical Bevices Net Better	O	1/11//2
MANU	FACTURER ASSISTANCE\GENERAL		
	Everything You Always Wanted to Know About Medical Device Requirements and Weren't	38	8/ 1/92
	Afraid to Ask		
434	Have a New Medical Device? Please Notify Us!	2	1/ 1/87
540	Special DSMA Report - Pertinent Voluntary Standards and Problem Definition Studies for Certain	11	3/3/87
	Pre-Amendment Class III Medical Devices	4	0/5/05
	List of Current CDRH Addresses for Report Submission and Ordering of CDRH Forms	4	9/ 5/95 6/ 1/88
570	We Are From the Government and We Are Here To Help You	3 13	0/ 1/88
574	Sterilization: Questions and Answers Summary of Requirements for the Manufacturer or Distribution of Substantially Equivalent Medical	13	6/28/84
374	Devices	1	0/20/04
644	Medical Device Regulatory Index	18	12/3/87
MDD D	OLICIES\ GUIDELINES		
	Graphs for: "Medical Device Reporting: An OVerview"	9	5/ 6/96
	MDR Guidance Document No. 4 - External Defibrillators	3	9/ 9/94
	World Wide Web (Internet)	1	4/22/96
	MDR Guidance Document No. 2 - Remedial Action Exception	3	6/12/95
	Tables for: "Medical Device Reporting for Manufacturers"	7	5/ 6/96
1988	Tables for: "Medical Device Reporting for Distributors"	6	5/6/96
1989	Tables for: "Medical Device Reporting for User Facilities"	5	5/ 6/96
	MDR Guidance Document No. 1 - Intraocular Lenses (IOL)	4	5/17/95
	MDR Guidance Document No. 3 - Needlesticks and Blood Exposure	3	5/11/94
	CDRH Electronic Docket (ED)	1	5/ 7/96
336	Federal Register, Final Rule: Medical Devices; Medical Device User Facility and Manufacturer	30	5/ 8/96
2700	Reporting, Certification and Registration (Docket 91N-0295)	4	5/10/06
3799 407	NTIS Medical Device Reporting - Baseline Report	4 2	5/10/96 4/22/96
407	Medical Device Reporting - Baseline Report Medical Device Reporting - Annual Certification	2	4/22/96
409	Medical Device Reporting - Annual Certification Medical Device Reporting - Semi-Annual User Facility Report	2	4/22/96
432	Medical Device Problem Reporting and the Health Care Professional	2	1/ 1/85
451	MDR Policy/Guidance for Endosseous Implant Devices	1	11/2/94
452	MDR Reporting Guidance for Breast Implants	2	2/ 1/92
4799	Health Care & Industry Organizations	3	5/ 7/96
509	Graphs for Medical Device Reporting: An Overview	24	6/ 5/96

Solution Pack Pac		DSMA Facts Domain		
Rule			<u>PAGES</u>	<u>DATE</u>
Rule				
599 CDRH Facts-On-Demand (F-O-D) 599 Draft Rebuilder/Refurbisher Trial Balloon FDA Discussion Document 598 Electronic Data Interchanges Strawman Standard for Adverse Event and Problem Reporting to the Food 6 6 3/93 and Drug Administration Center for Biologies, Drugs and Devices 973 Abbreviated Instructions for completing mandatory Medwatch Form 3500A **MEDWATCH INFORMATION** 799 MDR Related Document Information 821 Instructions for Completing Form 3500A (Specific to Medical Device Reporting) With Coding 822 12/15/9 Manual for Form 3500A - Med Watch MDR 834 MEDWATCH FDA Form 3500A; for use by User Facilities, Distributors and Manufacturers for 835 Mathematical Devices Regulatory Workshop 836 MEDWATCH FDA Form 3500A; for use by User Facilities, Distributors and Manufacturers for 837 Manual for Form 3500A; for use by User Facilities, Distributors and Manufacturers for 838 MEDWATCH FDA Form 3500A; for use by User Facilities, Distributors and Manufacturers for 839 Canadian Medical Devices Regulatory Workshop 840 Canadian Medical Devices Regulatory Workshop 851 MBW Workshop on Reclassification of Pre-Amendment Class III Devices; June 7, 1996 **ODE/BLUE BOOK*** **ODE/BLUE BOOK** **OOF*** **OPMA/510(k): Expedited Review (#G94-2)* **O1 PMA/510(k): Expedited Review of Submissions for Diagnostic Ultrasound Equipment & Related measurement policy of Investigational Devices (MG90-2)* **O13 Consolidated Review of Submissions for Lasers and Accessories (#G90-1).* **O14 Review of Final Draft Medical Device Labeling (#P91-4)* **O15 Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (MD95-2).* **O15 Interstigational Devices (MD95-2).* **O16 Attachment A to #D95-2; Interagency Agreement Regarding Reimbursement Categorization of Prestigational Devices (MD95-2).* **ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - 1 5/15/87 **Blue Book Memo G87-2.* **O16 Mentor Program (#A90-3).* **29 PMA Filing Decisions **30	557		50	12/ 1/91
599Draft Rebuilder/Refurbisher Trial Balloon FDA Discussion Document139/29/95845Electronic Data Interchange Strawman Standard for Adverse Event and Problem Reporting to the Food966/3/93973Abbreviated Instructions for completing mandatory Medwatch Form 3500A15/10/96MEDWATCH INFORMATION799MDR Related Document Information8212/15/9853Instructions for Completing Form 3500A (Specific to Medical Device Reporting) With Coding Manual for Form 3500A - Med Watch MDR212/15/9854MEDWATCH FDA Form 3500A: for use by User Facilities, Distributors and Manufacturers for Mandatory Reporting212/15/9NON-DSMA WORKSHOPS212/13/91879Canadian Medical Devices Regulatory Workshop212/13/92879Canadian Medical Devices Regulatory Workshop212/13/9974HIMA Workshop on Reclassification of Pre-Amendment Class III Devices; June 7, 199645/20/94ODE/BLUE BOOK007PMA/510(k) Expedited Review (#G94-2)410/19/9031Consolidate Review of Submissions for Lasers and Accessories (#G90-1)410/19/9032Review of Final Draft Medical Device Labeling (#P91-4)28/29/91033Review of Final Draft Medical Device Labeling (#P91-4)28/29/91104Hipmennation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2)99/15/95126ODE Regulatory Information for the Office of Compliance - Information	5799		1	4/22/96
set Electronic Data Interchange Strawman Standard for Adverse Event and Problem Reporting to the Food 6/ 3/93 and Drug Administration Center for Biologics, Drugs and Devices 73 Abbreviated Instructions for completing mandatory Medwarch Form 3500A 1 5/ 1/96				
### Abreviated Instructions for completing mandatory Medwatch Form 3500A 1 5/1/96 ### MEDWATCH INFORMATION 1 5/10/96 ### MDR Related Document Information 1 5/10/96 ### MDR Related Document Information 2 12/15/9 ### Manual for Form 3500A - Med Watch MDR ### Manual for Form 3500A - Med Watch MDR ### Manual for Form 3500A - Med Watch MDR ### Manual for Form 3500A - Med Watch MDR ### Manual for Form 3500A - Med Watch MDR ### Manual for Form 3500A - Med Watch MDR ### Manual for Form 3500A - Med Watch MDR ### Manual for Form 3500A - Med Watch MDR ### Manual for Form 3500A - Med Watch MDR ### Manual for Form 3500A - Med Watch MDR ### Manual for Form 3500A - Med Watch MDR ### MANUAL HIPD - MORE ### MANUAL H				
MEDWATCH INFORMATION 79 MDR Related Document Information 82 12/15/9 835 Instructions for Completing Form 3500A (Specific to Medical Device Reporting) With Coding 840 Manual for Form 3500A - Med Watch MDR 854 MEDWATCH FDA Form 3500A; for use by User Facilities, Distributors and Manufacturers for Manual for Form 3500A; for use by User Facilities, Distributors and Manufacturers for Wandatory Reporting 855 Manual for Form 3500A; for use by User Facilities, Distributors and Manufacturers for Wandatory Reporting 856 MEDWATCH FDA Form 3500A; for use by User Facilities, Distributors and Manufacturers for Wandatory Reporting 857 Mandatory Reporting 858 MEDWATCH FDA Form 3500A; for use by User Facilities, Distributors and Manufacturers for Wandatory Reporting 859 Manual for Form 3500A - Med Watch MDR 850 MeDWAKSHOPS 1879 Canadian Medical Devices Regulatory Workshop 260 Medical Devices Regulatory Workshop 270 Manual Medical Devices Regulatory Workshop 280 Medical Devices Regulatory Workshop 880 Medical Devices Regulatory Workshop 881 MINA Workshop on Reclassification of Pre-Amendment Class III Devices; June 7, 1996 882 Medical Review of Submissions for Diagnostic Ultrasound Equipment & Related measurement Period Medical Devices (Ref90-2) 883 Review of Final Draft Medical Device Labeling (#P91-4) 884 Review of Final Draft Medical Device Labeling (#P91-4) 885 Medical Review of Final Draft Medical Devices (#P91-4) 886 Review of Final Draft Medical Device Labeling (#P91-4) 887 Medical Devices (#D95-2) 888 Medical Review of Final Draft Medical Devices (#P91-4) 889 Medical Devices (#D95-2) 880 Memore Facilities, Distributors and Manufacturers for Medical Devices (#P95-2) 880 Memore Facilities, Distributors and Manufacturers for Medical Devices (#P95-2) 881 Medical Devices (#P95-2) 882 Medical Review of Submissions for Lasers and Accessories (#R90-1) 883 Medical Review of Submissions for Lasers and Accessories (#R90-1) 884 Review of Final Draft Medical Devices (#P95-2) 885 Medical Review of Final				
799 MDR Related Document Information 1 5/10/96 823 Instructions for Completing Form 3500A (Specific to Medical Device Reporting) With Coding Manual for Form 3500A. Med Watch MDR 12/15/9 Manual for Form 3500A. Med Watch MDR 12/15/9 Manual for Form 3500A; for use by User Facilities, Distributors and Manufacturers for Mandatory Reporting 12/15/9 Mandatory Reporting 12/15/9 Mandatory Reporting 12/15/9 Mandatory Reporting 12/13/9 18/19 Canadian Medical Devices Regulatory Workshop 2 12/13/9 18/19 Canadian Medical Devices Regulatory Workshop 2 12/13/9 18/1	973		1	5/ 1/96
799 MDR Related Document Information 1 5/10/96 823 Instructions for Completing Form 3500A (Specific to Medical Device Reporting) With Coding Manual for Form 3500A. Med Watch MDR 12/15/9 Manual for Form 3500A. Med Watch MDR 12/15/9 Manual for Form 3500A; for use by User Facilities, Distributors and Manufacturers for Mandatory Reporting 12/15/9 Mandatory Reporting 12/15/9 Mandatory Reporting 12/15/9 Mandatory Reporting 12/13/9 18/19 Canadian Medical Devices Regulatory Workshop 2 12/13/9 18/19 Canadian Medical Devices Regulatory Workshop 2 12/13/9 18/1	MEDW	ATCH INFORMATION		
853 Instructions for Completing Form 3500A (Specific to Medical Device Reporting) With Coding Manual for Form 3500A - Med Watch MDR 2 12/15/9 Manual for Form 3500A - Med Watch MDR 854 MEDWATCH FDA Form 3500A; for use by User Facilities, Distributors and Manufacturers for Mandatory Reporting 2 12/15/9 Mandatory Reporting NON-DSMA WORKSHOPS 1879 Canadian Medical Devices Regulatory Workshop 2 12/13/9 974 HIMA Workshop on Reclassification of Pre-Amendment Class III Devices; June 7, 1996 2 12/13/9 975 HIMA Workshop on Reclassification of Pre-Amendment Class III Devices; June 7, 1996 2 6/ 7/96 ODE\(SLUE BOOK\() 4 5/20/94 030 Consolidated Review of Submissions for Diagnostic Ultrasound Equipment & Related measurement Devices (#G90-2) 4 10/19/9 031 Consolidated Review of Submissions for Lasers and Accessories (#G90-1). 4 10/19/9 033 Review of Final Draft Medical Device Labeling (#P91-4) 2 8/29/91 035 Review of Final Draft Medical Devices (#K91-1) 2 8/29/91 106 Huse Book 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices 5			1	5/10/96
Manual for Form 3500A - Med Watch MDR			82	
NON-DSMA WORKSHOPS 1879 Canadian Medical Devices Regulatory Workshop 2 12/13/9 2879 Canadian Medical Devices Regulatory Workshop 2 12/13/9 974 HIMA Workshop on Reclassification of Pre-Amendment Class III Devices; June 7, 1996 2 6/7/96 ODE/BLUE BOOK 4 5/20/94 030 Consolidated Review (#G94-2) 4 10/19/9 031 Consolidated Review of Submissions for Diagnostic Ultrasound Equipment & Related measurement 4 10/19/9 034 Review of Final Draft Medical Device Labeling (#P91-4) 2 8/29/91 035 Review of Final Draft Medical Device Labeling (#P91-4) 2 8/29/91 106 Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2) 5 9/15/95 16 Blue Book: 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices 9-11/95 9 9/15/95 216 Blue Book: 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices 9-11/95 9 9/15/95 216 Blue Book Memo G87-2 9 9/15/95				
NON-DSMA WORKSHOPS 1879 Canadian Medical Devices Regulatory Workshop 2879 Canadian Medical Devices Regulatory Workshop 2879 Canadian Medical Devices Regulatory Workshop 3974 HIMA Workshop on Reclassification of Pre-Amendment Class III Devices; June 7, 1996 2 6/7/96 ODE\BLUE BOOK 007 PMA\s10(k) Expedited Review (#G94-2) 030 Consolidate Review of Submissions for Diagnostic Ultrasound Equipment & Related measurement Devices (#G90-2) 031 Consolidate Review of Submissions for Lasers and Accessories (#G90-1). 4 10/19/9 032 Review of Final Draft Medical Device Labeling (#P91-4) 033 Review of Final Draft Medical Device Labeling (#P91-4) 034 Review of Final Draft Medical Device Labeling (#P91-4) 035 Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) 036 Review of 510(k)s for International Standard ISO-10993, "Biological Evaluation of Medical Devices A29/91 037 Review of The PDA\s14 CFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2) 038 Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) 039 Part 1: Evaluation and Testing" 040 Attachment A to #D95-2; Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2) 051 Regulatory Information for the Office of Compliance - Information Sharing Procedures - Blue Book Memo G87-2 070 DE Regulatory Information for the Office of Compliance - Information Sharing Procedures - 1 5/15/87 071 Blue Book Memo G87-2 072 Training Checklist for New Reviewers (#A90-4) 073 PMA Filing Decisions 074 PMA Filing Decisions 075 PMA Filing Decisions 076 PMA Filing Decisions 077 PMA Filing Decisions 077 PMA Filing Decisions 077 PMA Filing Pecisions 078 PMA Filing Pecisions 079 PMA Filing Pecisions 070 PMA Filing Pecisions 070 PMA Filing Pecisions 070 PMA Filing Pecisions 071 PMA Filing Pecisions 071 PMA Filing Pecisions 071 PMA Filing Pecisions 072 PMA Filing Pecisions 073 PMA Filing Pecisions 074 PMA Filing Pecisions 075 PMA Filing Pecisions 076 PMA Filing Pecisions 077 PMA Filing Pec	854	MEDWATCH FDA Form 3500A; for use by User Facilities, Distributors and Manufacturers for	2	12/15/9
1879 Canadian Medical Devices Regulatory Workshop 2 12/13/9		Mandatory Reporting		
1879 Canadian Medical Devices Regulatory Workshop 2 12/13/9	NON-D	SMA WORKSHOPS		
2 12/13/9 974 HIMA Workshop on Reclassification of Pre-Amendment Class III Devices; June 7, 1996 2 6/7/96 ODE\BLUE BOOK 007 PMA/510(k) Expedited Review (#G94-2) 4 5/20/94 030 Consolidate Review of Submissions for Diagnostic Ultrasound Equipment & Related measurement Devices (#G90-2) 4 10/19/9 031 Consolidate Review of Submissions for Lasers and Accessories (#G90-1). 4 10/19/9 033 Review of Final Draft Medical Device Labeling (#P91-4) 2 8/29/91 035 Review of Final Draft Medical Device Labeling (#P91-4) 2 8/29/91 1106 Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2) 1106 Blue Book: 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" 2106 Attachment A to #D95-2; Interagency Agreement Pagarding Procedures Blue Book Memo G87-2 280 Panel Review of "Me-Too" Devices 1 7/1/86 289 Guidance on the Center for Devices and Radiological Health's Premarket Notification Review 16 6/30/86 Program 291 ODE Mentor Program (#A90-3) 2 5/4/90 292 Training Checklist for New Reviewers (#A90-4) 3 5/18/90 301 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness (#P86-1) 3 1/27/86 302 PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1) 3 1/27/86 304 Criteria for Panel Review PMA Supplements 6 1/30/86 305 Review and Approval of PMAs of Licensees 3 1 6/3/39/89 306 Panel Report and Recommendations on PMA Approvals 5 16/3/39/89 307 Panel Report and Recommendations on PMA Approvals 5 16/3/39/89 308 510(k) Sign-off Procedures; Blue Book Memo K94-2 4 6/3/39/89			2	12/13/9
ODE\BLUE BOOK ODE\BLUE BOOK OO7 PMA/510(k) Expedited Review (#G94-2) OS Consolidate Review of Submissions for Diagnostic Ultrasound Equipment & Related measurement Devices (#G90-2) OS Consolidate Review of Submissions for Lasers and Accessories (#G90-1). OS Review of Final Draft Medical Device Labeling (#P91-4) OS Review of Final Draft Medical Device Labeling (#P91-4) OS Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k)s for Computer Controlled Medical Devices (#K91-1) OS Review of 10(k) Sign-off Procedures (#K90-4) OS Review and Approval of PMA Supplements Office of General Counsel (OCG) Review of PMA Approvals OF Panel Report and Recommendations on PMA Appro		· · · · · · · · · · · · · · · · · · ·		
007 PMA/510(k) Expedited Review (#G94-2) 030 Consolidate Review of Submissions for Diagnostic Ultrasound Equipment & Related measurement Devices (#G90-2) 031 Consolidated Review of Submissions for Lasers and Accessories (#G90-1). 032 Review of Final Draft Medical Device Labeling (#P91-4) 033 Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) 035 Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) 036 Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2) 037 Investigational Devices (#D95-2) 038 Attachment A to #D95-2; Interagency Agreement Pair I: Evaluation and Testing: 039 Poly15/95 030 ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - Devices Agreement Pair Blue Book Memo G87-2 039 Panel Review of "Me-Too" Devices and Radiological Health's Premarket Notification Review Program Program (#A90-3) 030 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness PMAs - Panel Review PMA Supplements PMA Supplements PMA Sign-Poroval and Recommendations on PMA Approvals PMA Filing Decisions PMAs of Licensees PMAs - Panel Review PMA Supplements PMAs PMA Filing Procedures; Blue Book Memo K94-2				6/ 7/96
007 PMA/510(k) Expedited Review (#G94-2) 030 Consolidate Review of Submissions for Diagnostic Ultrasound Equipment & Related measurement Devices (#G90-2) 031 Consolidated Review of Submissions for Lasers and Accessories (#G90-1). 032 Review of Final Draft Medical Device Labeling (#P91-4) 033 Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) 035 Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) 036 Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2) 037 Investigational Devices (#D95-2) 038 Attachment A to #D95-2; Interagency Agreement Pair I: Evaluation and Testing: 039 Poly15/95 030 ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - Devices Agreement Pair Blue Book Memo G87-2 039 Panel Review of "Me-Too" Devices and Radiological Health's Premarket Notification Review Program Program (#A90-3) 030 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness PMAs - Panel Review PMA Supplements PMA Supplements PMA Sign-Poroval and Recommendations on PMA Approvals PMA Filing Decisions PMAs of Licensees PMAs - Panel Review PMA Supplements PMAs PMA Filing Procedures; Blue Book Memo K94-2	ODF\RI	LUE ROOK		
Consolidate Review of Submissions for Diagnostic Ultrasound Equipment & Related measurement Devices (#G90-2) O31 Consolidated Review of Submissions for Lasers and Accessories (#G90-1). Review of Final Draft Medical Device Labeling (#P91-4) Review of Final Draft Medical Device Labeling (#P91-4) Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2) I64 Blue Book: 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" 2106 Attachment A to #D95-2; Interagency Agreement DEVICE Regulatory Information for the Office of Compliance - Information Sharing Procedures - 1 5/15/87 Blue Book Memo G87-2 280 Panel Review of "Me-Too" Devices Guidance on the Center for Devices and Radiological Health's Premarket Notification Review of Medical Devices of Sologian (#A90-3) DEF Mentor Program (#A90-3) DEF Mentor Program (#A90-3) PMA Filing Decisions Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1) Training Checklist for Panel Review PMA Supplements Criteria for Panel Review PMA Supplements Review and Approval of PMAs of Licensees Part 1: Evaluation of Summaries of Safety and Effectiveness (#P86-1) PARE Filing Decisions Review and Approval of PMAs of Licensees Review and Approval of PMAs of Licensees Filing Decisions Review and Approval of PMAs of Licensees Review and Approval of PMAs of Licensees Filing Decisions Review and Approval of PMAs of Licensees Review and Approval of PMAs of Licensees Filing Decisions Review and Approval of PMAs of Licensees Review and Approval of PMAs of Licensees Filing Decisions Review and Approval of PMAs of Licensees			1	5/20/94
Devices (#G90-2) O31 Consolidated Review of Submissions for Lasers and Accessories (#G90-1). Review of Final Draft Medical Device Labeling (#P91-4) Review of Final Draft Medical Device Labeling (#P91-4) Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2) I64 Blue Book: 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" 2106 Attachment A to #D95-2; Interagency Agreement ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - Blue Book Memo G87-2 Bue Book Memo G87-2 Bue Book Memo G87-2 Bue Review of "Me-Too" Devices Guidance on the Center for Devices and Radiological Health's Premarket Notification Review program ODE Mentor Program (#A90-3) DE Mentor Program (#A90-3) Training Checklist for New Reviewers (#A90-4) PMA Filing Decisions Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness DMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#R86-1) Training Checklist Program (#A90-3) Criteria for Panel Review PMA Supplements Criteria for Panel Review PMA Supplements Review and Approval of PMAs of Licensees 3 10/22/9 Panel Report and Recommendations on PMA Approvals 5 10(k) Sign-off Procedures; Blue Book Memo K94-2				
034Review of Final Draft Medical Device Labeling (#P91-4)28/29/91035Review of 510(k)s for Computer Controlled Medical Devices (#K91-1)28/29/911106Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2)59/15/95164Blue Book: 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"65/1/952106Attachment A to #D95-2; Interagency Agreement99/15/95276ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - Blue Book Memo G87-215/15/87280Panel Review of "Me-Too" Devices17/1/86289Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program166/30/86291ODE Mentor Program (#A90-3)25/4/90292Training Checklist for New Reviewers (#A90-4)35/18/90297PMA Filing Decisions135/18/90301Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness27/25/86302PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1)31/27/86304Criteria for Panel Review PMA Supplements61/30/86305Review and Approval of PMAs of Licensees31/02/2/9306Panel Report and Recommendations on PMA Approvals74/18/86308510(k) Sign-off Procedures; Blue Book Memo K94-246/3		Devices (#G90-2)		
Review of 510(k)s for Computer Controlled Medical Devices (#K91-1) Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2) Blue Book: 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" 2106 Attachment A to #D95-2; Interagency Agreement 9 9/15/95 276 ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - Blue Book Memo G87-2 280 Panel Review of "Me-Too" Devices 1 7/1/86 289 Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program 291 ODE Mentor Program (#A90-3) 2 5/4/90 271 Taining Checklist for New Reviewers (#A90-4) 3 5/18/90 292 Training Checklist for New Reviewers (#A90-4) 3 5/18/90 293 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness 2 7/25/86 304 Criteria for Panel Review PMA Supplements 6 1/30/86 305 Review and Approval of PMAs of Licensees 3 10/22/9 306 Panel Report and Recommendations on PMA Approvals 7 4/18/86 307 Slock Sign-off Procedures; Blue Book Memo K94-2 4 6/3/94				
Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices (#D95-2) 164 Blue Book: 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" 2106 Attachment A to #D95-2; Interagency Agreement ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - Blue Book Memo G87-2 280 Panel Review of "Me-Too" Devices Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program 291 ODE Mentor Program (#A90-3) 292 Training Checklist for New Reviewers (#A90-4) 293 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness 304 Office of General Counsel (OCG) Review of PMA Summaries of Safety and Effectiveness (#P86-1) 305 Review and Approval of PMAs of Licensees 306 Panel Report and Recommendations on PMA Approvals 307 Safety and Recommendations on PMA Approvals 308 S10(k) Sign-off Procedures; Blue Book Memo K94-2 4 6/3/94				
of Investigational Devices (#D95-2) 164 Blue Book: 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" 2106 Attachment A to #D95-2; Interagency Agreement 9 9/15/95 276 ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - 1 5/15/87 Blue Book Memo G87-2 280 Panel Review of "Me-Too" Devices 1 7/1/86 289 Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program 291 ODE Mentor Program (#A90-3) 2 5/4/90 292 Training Checklist for New Reviewers (#A90-4) 3 5/18/90 297 PMA Filing Decisions 13 5/18/90 301 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness 2 7/25/86 302 PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1) 3 1/27/86 304 Criteria for Panel Review PMA Supplements 6 1/30/86 305 Review and Approval of PMAs of Licensees 3 10/22/9 306 Panel Report and Recommendations on PMA Approvals 7 4/18/86 308 510(k) Sign-off Procedures; Blue Book Memo K94-2 4 6/3/94				
Part 1: Evaluation and Testing" 2106 Attachment A to #D95-2; Interagency Agreement 9 9/15/95 276 ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - 1 5/15/87 Blue Book Memo G87-2 280 Panel Review of "Me-Too" Devices 1 7/ 1/86 289 Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program 291 ODE Mentor Program (#A90-3) 2 5/ 4/90 292 Training Checklist for New Reviewers (#A90-4) 3 5/18/90 297 PMA Filing Decisions 13 5/18/90 301 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness 2 7/25/86 302 PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1) 3 1/27/86 304 Criteria for Panel Review PMA Supplements 6 1/30/86 305 Review and Approval of PMAs of Licensees 3 10/22/9 306 Panel Report and Recommendations on PMA Approvals 7 4/18/86 308 510(k) Sign-off Procedures; Blue Book Memo K94-2 4 6/ 3/94	1106		5	9/15/95
2106 Attachment A to #D95-2; Interagency Agreement 276 ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - Blue Book Memo G87-2 280 Panel Review of "Me-Too" Devices 289 Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program 291 ODE Mentor Program (#A90-3) 292 Training Checklist for New Reviewers (#A90-4) 293 PMA Filing Decisions 301 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness 302 PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1) 304 Criteria for Panel Review PMA Supplements 305 Review and Approval of PMAs of Licensees 306 Panel Report and Recommendations on PMA Approvals 307 Sign-off Procedures; Blue Book Memo K94-2 308 S10(k) Sign-off Procedures; Blue Book Memo K94-2	164	Blue Book: 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Device	s 6	5/ 1/95
ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - Blue Book Memo G87-2 Panel Review of "Me-Too" Devices Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program ODE Mentor Program (#A90-3) Training Checklist for New Reviewers (#A90-4) PMA Filing Decisions Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness OFfice of General Counsel (OCG) Review of Safety and Effectiveness (#P86-1) Criteria for Panel Review PMA Supplements Review and Approval of PMAs of Licensees Review and Recommendations on PMA Approvals 5/18/70				
Blue Book Memo G87-2 280 Panel Review of "Me-Too" Devices Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program 291 ODE Mentor Program (#A90-3) 292 Training Checklist for New Reviewers (#A90-4) 293 PMA Filing Decisions 301 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness 302 PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1) 304 Criteria for Panel Review PMA Supplements 305 Review and Approval of PMAs of Licensees 306 Panel Report and Recommendations on PMA Approvals 510(k) Sign-off Procedures; Blue Book Memo K94-2 4 6/ 3/94	2106	Attachment A to #D95-2; Interagency Agreement	9	9/15/95
Panel Review of "Me-Too" Devices Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program 291 ODE Mentor Program (#A90-3) 292 Training Checklist for New Reviewers (#A90-4) 293 PMA Filing Decisions 301 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness 302 PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1) 304 Criteria for Panel Review PMA Supplements 305 Review and Approval of PMAs of Licensees 306 Panel Report and Recommendations on PMA Approvals 307 Sign-off Procedures; Blue Book Memo K94-2 308 S10(k) Sign-off Procedures; Blue Book Memo K94-2 309 Approval of PMAs of Licensees 309 Approval of Procedures; Blue Book Memo K94-2	276	ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures -	1	5/15/87
Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program 291 ODE Mentor Program (#A90-3) 292 Training Checklist for New Reviewers (#A90-4) 293 PMA Filing Decisions 301 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness 302 PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1) 304 Criteria for Panel Review PMA Supplements 305 Review and Approval of PMAs of Licensees 306 Panel Report and Recommendations on PMA Approvals 307 Approvals 308 510(k) Sign-off Procedures; Blue Book Memo K94-2 309 Banel Report and Recommendations on PMA Approvals 309 Approval of Procedures; Blue Book Memo K94-2 300 Banel Report and Recommendations on PMA Approvals 300 Approval of Procedures; Blue Book Memo K94-2				
Program 291 ODE Mentor Program (#A90-3) 292 Training Checklist for New Reviewers (#A90-4) 293 PMA Filing Decisions 301 Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness 302 PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1) 304 Criteria for Panel Review PMA Supplements 305 Review and Approval of PMAs of Licensees 306 Panel Report and Recommendations on PMA Approvals 307 Al 18/86 308 510(k) Sign-off Procedures; Blue Book Memo K94-2 308 4 6/3/94			1	
291ODE Mentor Program (#A90-3)25/ 4/90292Training Checklist for New Reviewers (#A90-4)35/18/90297PMA Filing Decisions135/18/90301Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness27/25/86302PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1)31/27/86304Criteria for Panel Review PMA Supplements61/30/86305Review and Approval of PMAs of Licensees310/22/9306Panel Report and Recommendations on PMA Approvals74/18/86308510(k) Sign-off Procedures; Blue Book Memo K94-246/ 3/94	289	· · · · · · · · · · · · · · · · · · ·	16	6/30/86
292Training Checklist for New Reviewers (#A90-4)35/18/90297PMA Filing Decisions135/18/90301Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness27/25/86302PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1)31/27/86304Criteria for Panel Review PMA Supplements61/30/86305Review and Approval of PMAs of Licensees310/22/9306Panel Report and Recommendations on PMA Approvals74/18/86308510(k) Sign-off Procedures; Blue Book Memo K94-246/ 3/94	291		2.	5/ 4/90
297PMA Filing Decisions135/18/90301Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness27/25/86302PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1)31/27/86304Criteria for Panel Review PMA Supplements61/30/86305Review and Approval of PMAs of Licensees310/22/9306Panel Report and Recommendations on PMA Approvals74/18/86308510(k) Sign-off Procedures; Blue Book Memo K94-246/ 3/94				
301Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness27/25/86302PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1)31/27/86304Criteria for Panel Review PMA Supplements61/30/86305Review and Approval of PMAs of Licensees310/22/9306Panel Report and Recommendations on PMA Approvals74/18/86308510(k) Sign-off Procedures; Blue Book Memo K94-246/ 3/94				
302PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1)31/27/86304Criteria for Panel Review PMA Supplements61/30/86305Review and Approval of PMAs of Licensees310/22/9306Panel Report and Recommendations on PMA Approvals74/18/86308510(k) Sign-off Procedures; Blue Book Memo K94-246/ 3/94		· ·		
304Criteria for Panel Review PMA Supplements61/30/86305Review and Approval of PMAs of Licensees310/22/9306Panel Report and Recommendations on PMA Approvals74/18/86308510(k) Sign-off Procedures; Blue Book Memo K94-246/ 3/94		·		
305Review and Approval of PMAs of Licensees310/22/9306Panel Report and Recommendations on PMA Approvals74/18/86308510(k) Sign-off Procedures; Blue Book Memo K94-246/ 3/94				
306Panel Report and Recommendations on PMA Approvals74/18/86308510(k) Sign-off Procedures; Blue Book Memo K94-246/ 3/94				
308 510(k) Sign-off Procedures; Blue Book Memo K94-2 4 6/3/94				
		•	4	
	3106	Attachment B to #D95-2; Criteria for Categorization of Investigational Devices	1	9/15/95

		IAGES	DATE		
328	Media Contacts (Blue Book #A86-1)	2	10/16/8		
330	Review of Laser Submissions (Blue Book Memo #88-1)	2	4/15/88		
331	Delegation of IDE Actions (Blue Book Memo #88-1)	5	4/26/88		
333	PMA Review Schedules (Blue Book Memo # P87-1)	2	3/31/88		
334	ODE Guidance Memoranda Table of Contents (Blue Book #T95-2_	4	3/29/96		
344	510(k) Quality Review Program (Blue Book Memo I96-1))	5	3/29/96		
357	Sabbatical Program for ODE Reviewers (#A86-2)	2	10/23/8		
360	Telephone Communications Between ODE Staff and Manufacturers (#I93-1)	6	1/29/93		
361	510(k) Sterility Review Guidance; (#K90-1)	6	2/12/90		
362	Review of IDEs for Feasibility Studies	6	5/17/89		
365	Integrity of the Medical Device Review Process (#I89-1)	1	10/25/8		
366	Assignment of Review Documents (#I90-2)	1	8/24/90		
	Policy Development and Review Procedures (#I90-1)	1	2/15/90		
369	Training for ODE Reviewers (#A89-1)	5	7/19/89		
376	ODE Regulatory Information for the Office of Compliance	1	5/15/87		
	510(k) Refuse to Accept Policy	10	6/30/93		
387	When PMA Supplements are Required (Blue Book Memo #90-1)	7	4/24/90		
388	ODE Peer Review Promotion Process (Blue Book Memo #A90-2)	2	4/24/90		
389	Approval of Speaking Engagements (Blue Book Memo #A90-1)	2	4/24/90		
401	510(k) Refuse to Accept Procedures (Blue Book Memo #K94-1)	3	5/20/94		
402	PMA Refuse to File Procedures (Blue Book Memo #P94-1)	4	5/20/94		
403	Premarket Approval Application (PMA) Closure	11	7/ 8/94		
404	PMA/510(k) Triage Review Procedures (Blue Book Memo #G94-1)	3	5/20/94		
404	Goals and Initiatives for the IDE Program (Blue Book Memo #D95-1)	8	7/12/95		
405	Blue Book Memo #K95-1 Cover Letter: 510(k) Requirement During Firm-Initiated Recalls -	6	11/21/9		
400	Attachment A: Guidance on Recall and Premarket Notification Review Procedures During	Ü	11/21/9		
	Firm-Initiated Recalls of Legally Marketed Devices				
4106	IDE List; Attachment C to D95-2, HCFA Reimbursement Categorization Determinations for FDA	6	10/31/9		
4100	Approved IDE's	U	10/31/9		
412	Document Control Procedures (Blue Book Memo #I90-3)	4	9/26/90		
413	510(k) Independent Quality Review Program (Blue Book Memo #I90-4)	2	10/31/9		
414	Device Labeling Guidance (Blue Book Memo #G91-1)	13	3/8/91		
443	Clinical Utility and Premarket Approval; (#P91-1)	3	5/ 3/91		
444	Panel Review of Premarket Approval Applications; (#P91-2)	4	5/ 3/91		
445	PMA Compliance Program; (#P91-3)	6	5/ 3/91		
446	Document Review Processing; (#I91-1)	6	2/12/92		
447	Integrity of Data and Information Submitted to ODE; (#I91-2)	1	5/29/91		
4859	Center for Devices and Radiological Health's Investigational Device Exemption (IDE) Refuse to	12	6/30/93		
	Accept Policy				
5859	PMA Refuse to File Policy	13	6/30/93		
587	Nondisclosure of Financially Sensitive Information (Blue Book Memo #I92-1)	5	3/ 5/92		
622	Training of Supervisors (Blue Book Memo #A92-1)	7	3/ 5/92		
931	Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment And	14	6/30/93		
	Allocating Review Resources (included with 926 - 930)				
	ODE\DCLD\ GUIDANCE				
051	Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies	16	2/ 1/94		

		INGLO	DITTE
	using IFA/IHA/RIA/ELISA		
082	Review Criteria for Blood Culture Systems	16	8/12/91
083	Review Criteria for Assessment of Serological In Vitro Diagnostic Devices for Detection of Serum	21	9/12/91
000	Antibodies to Borrelia Burgdorferi [Lyme Disease]		>/ 1 = /> 1
095	Points to Consider for Collection of Data in Support of In Vitro Device Submissions for 510(k)	10	9/26/94
0,2	Clearance	10)/ _ 0// .
152	Review Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using	24	8/31/95
	Various Methodologies		0,01,70
272	Assessing the Safety/Effectiveness of Home-use In Vitro Diagnostic Devices (IVDs): Points to	14	10/ 1/88
	Consider Regarding Labeling and Premarket Submissions		10, 1,00
285	Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use	44	8/ 2/94
339	Premarket Notification - Consistency of Reviews	2	2/28/89
364	Draft Guidance for Submission of Immunohistochemistry Applications to FDA/ cover letter	46	4/17/95
417	Review Criteria for Assessment of Cytogenic Analysis Using Automated and Semi-Automated	15	7/15/91
,	Chromosome Analyzers		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
459	Review Criteria for Assessment of Alpha-Fetoprotein (AFP) In Vitro Diagnostic Devices for Fetal	34	7/15/94
	Open Neural Tube Defects Using Immunological Test Methodologies		,,,,
475	Draft Guidance for 510(k) Submission of Lymphocyte Immunophenotyping Monoclonal Antibodies	8	9/26/91
494	Certification Program for In Vitro Diagnostic Devices Labeled "For Investigational Use Only"	8	10/17/9
518	Review Criteria for Assessment of Hepatitis A Virus Total & IgM Antibody - In Vitro Diagnostic	12	11/21/9
	Devices		
527	Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Antibodies to Viral Agents	15	8/ 1/92
553	Cover Letter/Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro	6	2/ 1/96
	Diagnostic Devices		
564	Guidance Criteria for Cyclosporine PMAs	17	1/24/92
588	Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to Helicobacter	13	9/17/92
	pylori		
592		14	9/27/95
	Devices (IVDs)		
603	Draft: Premarketing Approval Review Criteria for Premarket Approval of Estrogen (ER) or	23	9/10/92
	Progesterone (PGR) Receptors In Vitro Diagnostic Devices Using Steroid Hormone Binding (SBA)		
	with Dextran-Coated Charcoal (DCC) Separation, Histochemical Receptor		
604		13	1/ 1/92
	Using Glucose Oxidase Methodology		
605	Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physician's Office Laboratory,	26	7/14/95
	and Home Use		
615	Draft FDA Guidance to Manufacturers of In Vitro Analytical Test Systems for Preparation of	59	12/17/9
	Premarket Submissions Implementing CLIA		
629	Review Criteria for Devices Assisting in the Diagnosis of C. Difficile Associated Diseases	10	5/31/90
631	Review Criteria for Assessment of Antimicrobial Susceptibility Devices	26	5/31/91
658	Draft Guidance Document for 510(k) Submission of Glycohemoglobin (Glycated or Glycosylated)	18	9/30/91
	Hemoglobin		
665	Draft Document entitled Proposed Format: Package Insert for Immunohistochemistry Products	36	5/12/92
770	Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies	13	5/15/92
	to Parvovirus B19		
772	Draft Guidance Document for 510(k) Submission of Fecal Occult Blood Tests	17	7/29/92
778	Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae i	n 17	1/ 1/92

		IAGES	DATE
	Clinical Specimen		
800	Review Criteria for Assessment of Allergen-Specific Immunoglobulin E (IEG) In Vitro Diagnostic	19	3/ 2/93
000	Devices Using Immunological Test Methodologies	17	31 2173
848	Review Criteria for Assessment of Anti-Nuclear Antibodies (ANA) In Vitro Diagnostic Devices	21	9/ 1/92
040	Using Indirect Immunofluorescence Assay (IFA), Immunodiffusion (IMD), and Enzyme Linked	21)/ 1/ <i>)</i> 2
027	Immunosorbant Assay (ELISA)	10	1/27/04
927	DCLD Tier Categorizations; Triage Lists (includes 931)	19	1/27/94
950	Draft Data Required for Commericatialization of Original Equipment Manufacturer, Secondary and	7	11/13/9
0.60	Generic Reagents for Automated Analyzers	1.77	7/05/04
968	Points to Consider for Cervical Cytology Devices	17	7/25/94
ODF/D	CRND\ GUIDANCE		
-	Draft Guidance for Format and Content for Premarket Notification [510(k)] and DCRND Screening	12	7/19/95
037	Checklist	12	1/19/93
054	Guide for 510(k) Review of Processed Human Dura Mater	5	6/26/90
		5	0/20/90
	Protocol for Dermal Toxicity Testing for Devices in Contact with Skin (Draft)	11	0/0/01
141	Automated Defibrillators: Operator's Shift Checklist and Manual Defibrillators: Operator's Shift	2	8/8/91
1.40	Checklist D. G. W. i. a. D. G. C. i. L. G. 5101 G. d. d. d.		0/1/04
	Draft Version 1 - Biofeedback Devices/Draft Guidance for 510k Content	6	8/ 1/94
	Tables for Draft Guidance for Implantable Cardioverter-Defibrillators	2	1/11/96
207	Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators	2	6/ 1/94
208	Draft Version Guide for Cortical Electrode 510(k) Content	5	8/10/92
209	Draft Version Guidance for Clinical Data to be Submitted for Premarket Approval Application for	8	8/20/92
	Cranial Electrotherapy Stimulators		-44.64
	Draft Version Cranial Perforator Guidance	8	7/13/94
	Draft Version Neuro Endoscope Guidance	10	7/ 7/94
215	Galvanic Skin Response Measurement Devices Draft Guidance for 510(k) Content	6	8/23/94
224	Draft Guidance: Human Heart Valve Allografts	35	6/21/91
300	Guide for TENS 510(k) Content (draft)	6	8/ 1/94
347	Premarket Notification [510(k)] Guide for Breathing Frequency Monitors (Apnea Monitors)	15	6/6/88
354	Technological Reporting for Powered Muscle Stimulator 510(k) (EMS)	9	1/ 1/92
370	Balloon Valvulopasty Guidance for the Submission of an IDE Application and a PMA Application	10	1/ 1/89
372	Implantable Pacemaker Lead Testing Guidance for the Submission of a Section 510(k) Notification	6	9/ 1/89
373	Guidelines for the Preparation and Contents of an IDE Application for Laser Devices Used in the	11	11/2/88
	Treatment of Atherosclerotic Disease		
374	Guidance for the Preparation and Content of Applications to the FDA for Ventricular Assist and Total	1 34	12/4/87
	Artificial Hearts		
375	Draft Replacement Heart Valves - Guidance for Data to be Submitted to the FDA in Support of	94	7/26/93
	Applications for Premarket Approval and Addendum		
377	Guidance for Safety and Effectiveness Data Required in Premarket Notification (510k) Applications	5	3/ 1/83
	for Blood Oxygenators		
378	PTCA Catheter System Testing Guidance for the Submission of an IDE Application and a PMA	10	2/ 1/89
	Application		
379	FDA Policy on Prosthetic Vascular Grafts and General Guidance for the Preparation of Market	14	9/20/88
	Clearance Applications		
380	Cardiovascular Ultrasound Indications For Use Statements	1	11/17/8
381	Guidelines for Submitting Data In Support of Premarket Notification [510(k)] Application for	9	1/ 1/90
	- **		

Arrhythmia Detectors Arrhythmia Detectors Arrhythmia Detectors Determining Equivalence of Intraortic Balloon Catheters Under the \$10(k) Regulation Arrhythmia Detectors Determining Equivalence of Intraortic Balloon Catheters Under the \$10(k) Regulation Arrhythmia Detectors Determining Equivalence of Intraortic Balloon Catheters Under the \$10(k) Regulation Arrhythmia Detectors Determining Equivalence of Intraortic Balloon Catheters Under the \$10(k) Regulation Arrhythmia Detectors Determining Equivalence of Intraortic Balloon Catheters Under the \$10(k) Regulation Determining Equivalence of Catheter (1948) Diddelines: Vascular Graft Manufacturer, Developer, or Representative (Letter) Diddelines: Vascular Graft Manufacturer, Developer, or Representative (Letter) Diddelines for Reviewer Guidinines - Tracheostomy Tubes Uidance for Chygen Conserving Device \$10(k) Review 73 BZD 868.5905 Non-continuous Ventilator Class II Class II Class II Class II Review of \$10(k) Notices for Carbon Dioxide Lasers for Neurosurgery Review of \$10(k) Notices for Carbon Dioxide Lasers for Neurosurgery Review of \$10(k) Notices for Carbon Dioxide Lasers for Neurosurgery Permarket Notification Permarket Notification Permarket Notification Paral Yersion Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Paral 3- Implant Model Guidance for Studies for Pain Therapy Devices General Considerations in the Design of Clinical Fexcerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Additional Guidance for Pain Therapy Devices General Considerations in the Design of Clinical Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Additional Guidance for Pain Therapy Devices General Considerations in the Design of Clinical Fexcerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Additional Guidance for Pain Therapy Devices General Considerations in the Design of Clinical Fexcerpts Related to E		DSMA Facts Domain		
Determining Equivalence of Intraaortic Balloon Catheters Under the 510(k) Regulation 3 12/489 17/290 17/290 18/290			<u>PAGES</u>	DATE
Determining Equivalence of Intraaortic Balloon Catheters Under the 510(k) Regulation 3 12/489 17/290 17/290 18/290		Arrhythmia Detectors		
383 Implantable Pacemaker Testing Guidance 9 1/12/90 385 Second Draft Proposed Standard for the Infant Apnea Monitor 67 10/189 391 Guidance: Vascular Graft Manufacturer, Developer, or Representative (Letter) 23 5/11/90 500 Draft Reviewer Guidance for Ventilators 30 7/195 510 Alaysis of Explanted Replacement Heart Valves 3 1/190 520 Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses 4 4/190 520 Guidance for Reviewing Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator 2 2/189 521 Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked 2 2/189 522 Response Stimulators 2 2 189 524 Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery 2 2 4 3/195 525 Electrode Recording Catheter Preliminary Guidance - Data to be Submitted to the FDA in Support 6 3/195 627 Draft Version - Gurdiac Ablation Preliminary Guidance - Data to be Submitted to the FDA in Support 6 3/195 628 Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch 18 11/193 <t< td=""><td>382</td><td>·</td><td>3</td><td>1/24/89</td></t<>	382	·	3	1/24/89
385Second Draft Proposed Standard for the Infant Apnea Monitor6710/189510Guidance: Vascular Graft Manufacturer, Developer, or Representative (Letter)325/11/90520Draft Reviewer Guidlance for Ventilators307/195530AnJossi of Explanted Replacement Heart Valves33/190532Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses44/190533Guidance for Cxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator22/189534Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked22535Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery22640Electrode Recording Catheter Preliminary Guidance - Data to be Submitted to the FDA in Support of Investigational Device Exemption Applications63/195637Draft Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants:59/12/94648Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch1811/193649Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch181/193653Recommended Test Methods Infant Apnea Monitor Standard49/193654Rationale For Requirements Infant Apnea Monitor Standard49/193655Draft 510(k) Checklist for Sterilization Wraps43/194676Draft 510(k) Checklist for Sterilization Wraps18/30/9			9	1/12/90
Similation Sim				
500 Draft Reviewer Guidance for Ventilators 510(k) Reviewer Guidines - Tracheostomy Tubes 510(k) Reviewer Guidance for Carbon Dioxide Lasers for Menary Park Park Park Park Park Park Park Park				
550510(k) Reviewer Guidlines - Tracheostomy Tubes1563Analysis of Explanted Replacement Heart Valves33/190522Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses44/190583Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator22/1/89584Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked22585Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery22602Electrode Recording Catheter Preliminary Guidance - Data to be Submitted to the FDA in Support of Investigational Device Exemption Applications63/1/95619Draft Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3 - Implant Model59/12/94627Draft Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3 - Implant Model111/193636Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Studies for Pain Therapy Devices - General Considerations in the Design of Clinical Studies for Pain Therapy Devices111/193646Rationale For Requirements Infant Apnea Monitor Standard49/193654Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea49/193654Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea49/193654Part to f 510(k) Checklist for Through-Put Process Indicators4<		• • •		
Analysis of Explanted Replacement Heart Valves Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator Class II Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators Electrode Recording Catheter Preliminary Guidance - Data to be Submitted to the FDA in Support of Premarket Notification Furalf Version Cardiac Ablation Preliminary Guidance - Data to be Submitted to the FDA in Support of Investigational Device Exemption Applications Part Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Process Indicators Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices P				
Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses 2 diddance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator 2 2/1/89 Class II 593 Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators 794 Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery 795 Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery 796 Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery 796 Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery 797 Remarket Notification 798 Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery 799 Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery 799 Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery 799 Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery 799 Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery 799 Review of 510(k) Notices for Paliminary Guidance - Data to be Submitted to the FDA in Support of Paliminary Guidance on Biocompatibility Requirements for Long Term Neurological Implants: 799 Premarket Notification 799 Poraft Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants: 790 Praft Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants: 790 Praft Ostudiance for Studies for Pain Therapy Devices - General Considerations in the Design of Clinical 790 Studies for Pain-Alleviating Devices 791 Studies for Pain-Alleviating Devices 791 Studies for Pain-Alleviating Devices 792 Studies for Pain-Alleviating Devices 793 Studies for Pain-Alleviating Appa Monitor Standard 794 Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea 795 Draft S10(k) Checklist for Sterilization Wraps 796 Draft S10(k) Checklist for Through-Put Process Indicators 797 Proft of Guidance for Nebulizers, Metered Dose Inhalers, Spacers		· · · · ·	3	3/ 1/90
Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator Class II Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery Electrode Recording Catheter Preliminary Guidance - Data to be Submitted to the FDA in Support of Premarket Notification Draft Version Cardiac Ablation Preliminary Guidance - Data to be Submitted to the FDA in Support of Investigational Device Exemption Applications Part Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants: 5 9/12/94 Part 3 - Implant Model Excepts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Guidance for Studies for Pain Therapy Devices - General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices Recommended For Requirements Infant Apnea Monitor Standard 44 9/ 1/93 Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea Monitor Standard 49 1/93 Monitor Standard Tart 510(k) Checklist for Sterilization Wraps 4 3/ 1/94 Part 6 510(k) Checklist for Sterilization Wraps 5 1/1/24/9 Part 6 510(k) Checklist for Through-Put Process Indicators 1 1 8/30/91 Proposed Guidance Governator 1 1 8/30/91 Reviewer's Guidance Oxygen Concentrator 1 1 8/30/91 Proposed Guidance For Nebulizers, Metered Dose Inhalers, Spacers and Actuators 5 1/1/99 Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology 5 1/193 Portic Guidance for the Preparation of Research and Marketing Applications for Vascular Graft 7 9 8/ 1/93 Prostheses and Cover Letter 1 Prostances and Cover Lett	582	• •	4	4/ 1/90
Response Stimulators Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery 2 Electrode Recording Catheter Preliminary Guidance - Data to be Submitted to the FDA in Support of Premarket Notification Draft Version Cardiac Ablation Preliminary Guidance - Data to be Submitted to the FDA in Support of Investigational Device Exemption Applications To Praft Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3 - Implant Model Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Guidance for Studies for Pain Therapy Devices - General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices Rationale For Requirements Infant Apnea Monitor Standard Recommended Test Methods Infant Apnea Monitor Standard Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea Monitor Standard Draft 510(k) Checklist for Sterilization Wraps Toraft of 510(k) Checklist for Through-Put Process Indicators Part of 510(k) Checklist for Sterilization Wraps Heated Humidifier Review Guidance Part of S10(k) Checklist for Sterilization Steril		Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilato		
Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery Electrode Recording Catheter Preliminary Guidance - Data to be Submitted to the FDA in Support of Premarket Notification Draft Version Cardiac Ablation Preliminary Guidance - Data to be Submitted to the FDA in Support of Investigational Device Exemption Applications Draft Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3 - Implant Model Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Guidance for Studies for Pain Therapy Devices -General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices Rationale For Requirements Infant Apnea Monitor Standard Recommended Test Methods Infant Apnea Monitor Standard Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea Monitor Standard Part 510(k) Checklist for Sterilization Wraps Draft 510(k) Checklist for Sterilization Wraps Part 510(k) Checklist for Through-Put Process Indicators Proposed Guidance Oxygen Concentrator Proposed Guidance for Ventilator Evaluations Catheter Guidance For Nebulizers, Metered Dose Inhalers, Spacers and Actuators Reviewer's Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Part Battery Guidelines Draft Battery Guidelines Draft Battery Guidelines Prostheses and Cover Letter Reviewer Guidance for Premarket Submissions Reviewer Guidance for Premarket Submissions Reviewer Guidance For Premarket Submissions Part of Guidance For Premarket Su	593	Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked	2	
Electrode Recording Catheter Preliminary Guidance - Data to be Submitted to the FDA in Support of Premarket Notification 16	594	•	2	
of Investigational Device Exemption Applications Draft Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3 - Implant Model Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Guidance for Studies for Pain Therapy Devices -General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices Rationale For Requirements Infant Apnea Monitor Standard Recommended Test Methods Infant Apnea Monitor Standard Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea Monitor Standard Draft 510(k) Checklist for Sterilization Wraps Draft of 510(k) Checklist for Through-Put Process Indicators Reviewer's Guidance Oxygen Concentrator Reviewer's Guidance For Ventilator Evaluations Reviewer Guidance for Ventilator Evaluations Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter Reviewer Guidance for Premarket Submissions DCRND Triage Lists (includes 931) DCRND Triage Lists (includes 931) DCRND Triage Lists (includes 931) Draft of Guidance Subject to Required Post Market Surveilannce		Electrode Recording Catheter Preliminary Guidance - Data to be Submitted to the FDA inSupport of	16	3/ 1/95
Part 3 - Implant Model Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch Guidance for Studies for Pain Therapy Devices -General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices Rationale For Requirements Infant Apnea Monitor Standard Recommended Test Methods Infant Apnea Monitor Standard Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea Monitor Standard Draft 510(k) Checklist for Sterilization Wraps Draft of 510(k) Checklist for Through-Put Process Indicators Reviewer's Guidance Govgen Concentrator Reviewer's Guidance for Ventilator Evaluations Catheter Guidance Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter Reviewer Guidance for Premarket Submissions DCRND Triage Lists (includes 931) DCRND Triage Lists (includes 931) Porous Coatings Subject to Required Post Market Surveilannce	619		6	3/ 1/95
640 Guidance for Studies for Pain Therapy Devices -General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices 646 Rationale For Requirements Infant Apnea Monitor Standard 657 Recommended Test Methods Infant Apnea Monitor Standard 658 Recommended Test Methods Infant Apnea Monitor Standard 659 Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea 650 Monitor Standard 651 Draft 510(k) Checklist for Sterilization Wraps 652 Additional Guidance for Sterilization Wraps 653 Draft 510(k) Checklist for Sterilization Wraps 654 Additional Guidance 655 Draft 610(k) Checklist for Through-Put Process Indicators 656 Aller Humidifier Review Guidance 657 Aller Proposed Guidance Oxygen Concentrator 658 Catheter Guidance Oxygen Concentrator 769 Proposed Guidance for Ventilator Evaluations 760 Catheter Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators 761 Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology 762 Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft 763 Prostheses and Cover Letter 764 Prostheses and Cover Letter 776 Prostheses and Cover Letter 777 Prostheses and Cover Letter 778 Prostheses and Cover Letter 788 Pockno Triage Lists (includes 931) 789 DcRND Triage Lists (includes 931) 780 Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed 780 Porous Coatings Subject to Required Post Market Surveilannce	627	Draft Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants:	5	9/12/94
640 Guidance for Studies for Pain Therapy Devices -General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices 646 Rationale For Requirements Infant Apnea Monitor Standard 647 Recommended Test Methods Infant Apnea Monitor Standard 648 Recommended Test Methods Infant Apnea Monitor Standard 649 Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea 650 Monitor Standard 651 Monitor Standard 652 Monitor Standard 653 Draft 510(k) Checklist for Sterilization Wraps 654 Additional Guidance for Sterilization Wraps 655 Monitor Standard 666 Prain Apnea 667 Monitor Standard 668 Monitor Standard 669 Draft of 510(k) Checklist for Through-Put Process Indicators 670 Draft of 510(k) Checklist for Through-Put Process Indicators 671 Heated Humidifier Review Guidance 671 Reviewer's Guidance Oxygen Concentrator 772 Proposed Guidance Oxygen Concentrator 773 Catheter Guidance 774 Suddance 775 Suddance Guidance for Ventilator Evaluations 775 Catheter Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators 776 Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology 777 Draft Battery Guidelines 778 Draft Battery Guidelines 779 Prostheses and Cover Letter 779 Reviewer Guidance for the Preparation of Research and Marketing Applications for Vascular Graft 779 Prostheses and Cover Letter 770 Prostheses and Cover Letter 771 Prostheses and Cover Letter 770 Prostheses and Cover Letter 770 Prostheses and Cover Letter 771 Prostheses and Cover Letter 770 Prostheses and Cover Letter 771 Prostheses and Cover Letter 771 Prostheses and Cover Letter 772 Prostheses and Cover Letter 773 Prostheses and Cover Letter 774 Prostheses and Cover Letter 775 Prostheses and Cover Letter 776 Prostheses and Cover Letter 777 Prostheses and Cover Le	638	Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch	18	11/1/93
Rationale For Requirements Infant Apnea Monitor Standard Recommended Test Methods Infant Apnea Monitor Standard Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea Monitor Standard Draft 510(k) Checklist for Sterilization Wraps Part 510(k) Checklist for Through-Put Process Indicators Heated Humidifier Review Guidance Reviewer's Guidance Oxygen Concentrator Reviewer's Guidance Oxygen Concentrator Reviewer Guidance for Ventilator Evaluations Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents Draft Battery Guidelines Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter Reviewer Guidance for Premarket Submissions PocRND Triage Lists (includes 931) Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveilannce	640	Guidance for Studies for Pain Therapy Devices -General Considerations in the Design of Clinical	15	5/12/88
Recommended Test Methods Infant Apnea Monitor Standard Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea Monitor Standard Total Draft 510(k) Checklist for Sterilization Wraps Draft 510(k) Checklist for Through-Put Process Indicators Heated Humidifier Review Guidance Reviewer's Guidance Oxygen Concentrator Proposed Guidance for Ventilator Evaluations Catheter Guidance Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Reviewer Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents Draft Battery Guidance for Premarket Submissions Prostheses and Cover Letter Reviewer Guidance for Premarket Submissions 4 11/193 DCRND Triage Lists (includes 931) Porous Coatings Subject to Required Post Market Surveilannce	646	· · · · · · · · · · · · · · · · · · ·	28	9/ 1/93
Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea Monitor Standard 763 Draft 510(k) Checklist for Sterilization Wraps 4 3/ 1/94 764 Draft of 510(k) Checklist for Through-Put Process Indicators 780 Heated Humidifier Review Guidance 781 Reviewer's Guidance Oxygen Concentrator 782 Proposed Guidance for Ventilator Evaluations 783 Catheter Guidance 784 Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators 785 Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators 786 Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators 787 Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology 786 Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents 787 Draft Battery Guidelines 788 Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft 789 Prostheses and Cover Letter 790 Reviewer Guidance for Premarket Submissions 790 DCRND Triage Lists (includes 931) 791 1/27/94 794 Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed 795 Porous Coatings Subject to Required Post Market Surveilannce			44	9/ 1/93
Draft of 510(k) Checklist for Through-Put Process Indicators Heated Humidifier Review Guidance Reviewer's Guidance Oxygen Concentrator Proposed Guidance for Ventilator Evaluations Catheter Guidance Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents Draft Battery Guidelines Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter Reviewer Guidance for Premarket Submissions DCRND Triage Lists (includes 931) Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveilannce		Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea	11	
780Heated Humidifier Review Guidance38/30/91781Reviewer's Guidance Oxygen Concentrator18/30/91782Proposed Guidance for Ventilator Evaluations36/4/85783Catheter Guidance25/15/91784Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators511/9/90846Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents655/1/93873Draft Battery Guidelines47/12/93885Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter798/1/93908Reviewer Guidance for Premarket Submissions4411/1/93926DCRND Triage Lists (includes 931)191/27/94946Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveilannce1410/25/9	763	Draft 510(k) Checklist for Sterilization Wraps	4	3/ 1/94
Reviewer's Guidance Oxygen Concentrator Proposed Guidance for Ventilator Evaluations Catheter Guidance Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents Prostheses and Cover Letter Reviewer Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter Reviewer Guidance for Premarket Submissions PORND Triage Lists (includes 931) Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveilannce	764	Draft of 510(k) Checklist for Through-Put Process Indicators	2	11/24/9
Proposed Guidance for Ventilator Evaluations Catheter Guidance Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents Praft Battery Guidelines Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter Reviewer Guidance for Premarket Submissions DCRND Triage Lists (includes 931) Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveilannce	780	Heated Humidifier Review Guidance	3	8/30/91
Proposed Guidance for Ventilator Evaluations Catheter Guidance Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents Praft Battery Guidelines Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter Reviewer Guidance for Premarket Submissions DCRND Triage Lists (includes 931) Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveilannce	781	Reviewer's Guidance Oxygen Concentrator	1	8/30/91
Catheter Guidance Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents B73 Draft Battery Guidelines B75 Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter B76 Prostheses and Cover Letter B77 Prostheses and Cover Letter B78 Reviewer Guidance for Premarket Submissions B79 Prostheses Cover Guidance for Premarket Submiss			3	6/4/85
 Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents Draft Battery Guidelines Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter Reviewer Guidance for Premarket Submissions DCRND Triage Lists (includes 931) Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveilannce 		•		
 Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents Draft Battery Guidelines Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter Reviewer Guidance for Premarket Submissions DCRND Triage Lists (includes 931) Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveilannce 	784	Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators	5	11/9/90
Draft Battery Guidelines 871 Draft Battery Guidelines 872 Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft 873 Prostheses and Cover Letter 974 Prostheses and Cover Letter 975 Reviewer Guidance for Premarket Submissions 976 DCRND Triage Lists (includes 931) 977 Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed 978 Porous Coatings Subject to Required Post Market Surveilannce	846	Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology	65	5/ 1/93
Prostheses and Cover Letter 908 Reviewer Guidance for Premarket Submissions 926 DCRND Triage Lists (includes 931) 927 Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveilannce 988 Reviewer Guidance for Premarket Submissions 999 11/27/94 199 1/25/9	873	Draft Battery Guidelines	4	7/12/93
926 DCRND Triage Lists (includes 931) 946 Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveilannce 927 Porous Coatings Subject to Required Post Market Surveilannce	885		79	8/ 1/93
946 Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed 14 10/25/9 Porous Coatings Subject to Required Post Market Surveilannce	908	Reviewer Guidance for Premarket Submissions	44	11/1/93
946 Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed 14 10/25/9 Porous Coatings Subject to Required Post Market Surveilannce	926	DCRND Triage Lists (includes 931)	19	1/27/94
		Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed		
	965		44	1/11/96

028 Guidance for the preparation of Premarket Notification [510(k)] for Resorbable Periodontal Barriers

7

033	Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants	16	11/11/9
085	Guidance Document for the Preparation of Premarket Notification 510(k) for Temporomandibular Joint Implants	19	1/23/95
086	Overview of Information Necessary for Premarket Notification Submission for Endosseous Implants	7	
087	Outline of Recommended Procedures for a Clinical Investigation of Endosseous Implants Under a 510(k)	6	
088	Outline of Recommended Procedures for Animal Laboratory Studies of Endosseous Implants	4	
090	510(k0 Information Needed for Hydroxyapatite Coated Titanium Endosseous Implants	3	7/ 6/93
091	510(k) Information Needed for Ti-Powder Coated Titanium Endosseous Implants	3	7/13/93
092	510(k) Information Needed for Metallurgical Endosseous Implants	2	8/12/93
093	Guidance Information on Surface Characteristics of Implant Metals	2	7/30/93
094	Guidance Information on Galvanic Corrosion of Implant Metals	2	8/ 2/93
107	Letter: Core Study for Silicone Breast Implants	3	1/11/96
108	Draft Guidance for the Preparation of a Premarket Notification [510(k)] Submission for Sun Protective Clothing	17	8/10/94
133	Device Considerations for Spinal Fixation Device Systems	11	8/20/93
144	Draft Guidance for Preparation of FDA Submissions of Silicone Gel-Filled Breast Prostheses	29	5/11/92
145	Draft 510(k) Checklist for Air Cleaners/Air Purifiers	3	9/ 1/94
146	Draft Guidance for Testing of Alternative Breast Prostheses (nonsilicone gel-filled)	11	9/ 1/94
163	Clarification on Cleaning Agents and General Purpose Disinfectants that Require a 510(k) Submission	2	5/ 3/95
165	Interim Guidance on Protein Content Labeling Claim for Latex Medical Gloves (with cover letter to medical glove manufacturers)	13	5/ 1/95
180	Draft Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices	4	3/28/95
1833	Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities	3	9/19/95
187	Draft Guidance Document for Femoral Stem Prostheses	15	8/ 1/95
1993		6	3/20/96
233	Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prosthetic	64	2/18/93
233	Knee Ligament	04	2/10/73
23/	Guidance Document for the Preparation of IDE and PMA Applications for Bone Growth Stimulator	29	8/12/88
234	Devices	2)	0/12/00
252	Guidance Document for Testing Biodegradable Fracture Fixation Implant Devices	12	4/ 1/93
307	Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for	14	7/26/95
	Submerged (Underwater) Exercise Equipment		1/20/73
314	Inclusion of Class II or Class III Type Devices in Surgical Kits Under 510(k) - (sutures)	2	0/11/06
315	Establishment of ODE Policy for Labeling Surgical Suture Size	4	3/11/86
325	Guidance Document for the Preparation of Premarket Notification [510(K)] Applications for Electromyograph Needle Electrodes	11	7/26/95
346	Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles	9	7/26/95
353	Guidance for the Arrangement and Content of a Premarket Approval (PMA) Apoplication for an Endosseous Implant for Prosthetic Attachment	23	5/16/89
355	Guidance Document for the Preparation of Premarket Notification for 510(k) for Ceramic Ball Hip Systems	9	1/10/95

386	Guidance on the Content and Organization of a Premarket Notification for a Medical Laser	27	6/ 1/95
392	Guidance on 510(k) Submission for Implanted Infusion Ports	26	10/ 1/90
424	Guidelines for the Premarket Testing and Labeling of Antimicrobial Agents for Medical Devices	22	11/18/8
436	Orthopedic Device Approval and Labeling	2	1/1/87
450	Guidance on the Content of Premarket Notification [510(k)] Submissions for Hypodermic Single Lumen Needles	16	4/ 1/93
453	Guidance Document for Testing Acetabular Cup Prostheses	16	5/ 1/95
532	Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses	47	1/18/95
556		11	7/ 1/95
576	Guidance on the Content and Format of Premarket Notification {510(k)} Submissions for Liquid	54	4/26/95
370	Chemical Germicides	51	1/20/55
636	Draft Guideline for Reviewing Spinal Fixation Device Systems	6	7/18/95
642	Guidance for the Preparation of A Premarket Notification 510(k) for Direct Filling Dental Composites	19	1/ 1/96
668	Draft Outline for a Guidance Document for Testing Orthopedic Bone Cement	5	11/1/93
689	Guidance document for the Preparation of Premarket Notification [510(k)] Applications for Beds	13	7/26/95
729	Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Immersion Hydrobaths	13	7/26/95
735	Guidance document for the Preparation of Premarket Notification [510(k)] Applications for Powered Tables and Multifunctional Physical Therapy Tables	13	7/26/95
762	Guidance document for the Preparation of Premarket Notification [510(k)] Applications for Communications Systems (Powered and Non-Powered) and Powered Environmental Control Systems	14	7/26/95
790	510(k) Guidance for Screw Type Endosseous Implant for Prosthetic Attachment	10	8/11/92
817	Checklists for Wound Dressing 510(k)/Interactive Wound and Burn Dressing IDE Submission	14	3/31/95
818	Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Therapeutic Massagers and Vibrators	11	7/26/95
821	Guidance on the Content of Premarket Notification [510(k)] Submissions for Piston Syringes	21	4/ 1/93
822	Guidance on the Content of Premarket Notification [510(k)] Submissions for Clinical Electronic Thermometers	18	3/ 1/93
823	Guidance on the Content of Premarket Notification [510(k)] Submissions for External Infusion	19	3/ 1/93
	Pumps		
824	Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters	26	3/16/95
827	Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement	8	4/28/94
828	Guidance document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices	11	7/26/95
830	Draft Guidance for the Preparation of Premarket Notification [510(k)] for Cemented Semi-Constrained Knee	9	4/ 1/93
832	Draft Guidance Document for the Preparation of Premarket Notification 510(k) Applications for Orthopedic Devices - The Basic Elements	9	3/28/95
833	Guidance on Premarket Notification [510(k) Submissions for Sterilizers Intended for Use in Health Care Facilities	34	3/ 1/93
881	Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities	23	8/ 1/93
888	Draft Guidance on Premarket Notifications [510(k)] Submissions for Surgical Gowns and Surgical	19	8/ 1/93

		<u>I AGES</u>	DATE
	Drapes		
895	Guidance on the Content and Format of Premarket Notification [510k)] Submissions for Sharps	8	10/ 1/93
073	Containers	O	10/ 1/75
902	Draft Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for	21	10/ 1/93
702	General Purpose Disinfectants	21	10/ 1/73
904	Draft 510(k) Guideline for General Surgical Electrosurgical Devices	19	5/10/95
909	Draft Guidance for Arthroscope and Accessory 510(k)s	7	5/ 1/94
914	Guidance Document for Testing Biodegradable Polymer Fracture Fixation Devices	16	5/12/95
915	Guidance Document for Testing Broadgradable Tolymer Tracture Tixation Devices Guidance Document for Testing Bone Anchor Devices	9	11/ 1/93
916	Guidance Document for Testing Bone Anchor Devices Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant	8	5/ 1/95
710	Components	o	3/ 1/93
929	DGRD Tier Categorization; Triage Lists (includes 931)	23	1/27/94
934	Draft Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for	34	3/ 1/95
934		34	3/ 1/93
940	Medical Devices with Sharps Injury Prevention Features Draft Guideline for Reviewing Pedicle Screw Spinal Fixation Device Systems intended for Severe	16	1/17/95
940	·	16	1/1//93
002	Spondylolisthesis Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints	1	3/29/96
993	Guidance on the Content of Pfemarket Notification [510(k)] Submissions for Protective Restraints	1	3/29/90
ODEID	ODI CHIDANCE		
•	OD\ GUIDANCE	1.2	c/12/05
	Guidance Document Multifocal Intraocular Lens IDEs: Preclinical and Clinical Use	13	6/13/95
079	Labeling Suggestions for Ultraviolet (UV) Light Absorbing Contact Lenses	2	9/16/87
109	Draft Clinical Guidance for the Preparation and Contents of an Investigational Device Exemption	12	6/ 8/90
	(IDE) Application for Excimer Laser Devices Used in Ophthalmic Surgery for Myopic		
	Photorefractive Keratectomy (PRK)		01.5104
256	Suggestions Contact Lens Product Labeling (Draft)	46	8/6/81
266	Testing the Nd: Yag Laser for Ophthalmic Surgery	12	8/ 1/83
275	Testing Guidance/Guidelines for Class III Soft Hydrophilic Contact Lens Solutions (Draft)	70	7/15/85
309	Safety and Labeling Requirements for Heat Disinfection Units used with soft contact lenses	14	5/22/86
310	IOL: Ultraviolet (UV) Absorbing Lens Labeling/Trade Names/Report Requir. for Ant. Chamber	12	5/16/86
212	Lenses/Submission of Manufact. Inform. for PMAs; UV-Absorbing IOL PMAs	0	5 / 2 0/05
	Annual Reports in Place of PMA Supplements for Contact Lens	9	7/29/85
	Report on Intraocular Lenses (IOLs) Adjunct Study	22	12/ 1/86
317	30 Day Approval of PMA Supplements for New Contact Lenses to Correct Astigmatism and	24	11/18/8
	Presbyopia		
318	Holders of PMAs for Daily Wear Lenses May Modify Labeling to Extend Powers and Dimensions	3	11/14/8
	Without Obtaining Approval: (Letter)		
319	New Procedures for Implementing Changes in Contact Lens Packaging Materials	3	11/18/8
320	New Procedures for Implementing Changes in Contact Lens Solution Packaging Materials	3	11/18/8
321	New Requirements for Investigations of Anterior Chamber Intraocular Lenses (IOL)	8	12/18/8
322	Adverse Reaction Reporting Requirements; Applicable to IOLs Investigations	3	1/18/90
394	IOL Guidance for Submitting Sterilant Residue Data for PMA's (Letter)	2	10/ 1/81
395	IOL Guidance for Types of Information Necessary When Submitting Summary of Safety and	13	11/9/81
	Effectiveness Data (Letter)		
	IOL: How Labeling Modification Should be Submitted to the FDA (Letter)	4	3/13/85
397	Waivers from Certain Requirements of the IOL Regulations	3	3/11/85
514	Proposed Draft Guidance for Photorefractive Keratectomy Laser Systems: IDE Studies and PMA	113	6/12/95
	Applications		

		INGLO	DITTE
767	Guidance Document Approval Requirements for IOLs with an Extended Power Range	10	1/6/95
793	Sutured Posterior Chamber Intraocular Lenses: Proposed Guidance	21	6/13/90
794	Intraocular Lens Adjunct Study Phase-Out	4	8/31/88
795	Guidelines for Intraocular Devices	39	6/9/80
930	DOD Tier Categorization; Triage List (includes 931)	5	1/27/94
943	Letter: All Contract Lens Manufacturers and Other Interested Persons: Procedures for Adding the	8	3/8/94
	Monovision Fitting Technique to the Labeling of Class III Single Vision Contact Lenses for		
	Managing Presbyopia		
ODE/D	RAERD\GUIDANCE		
-	Guidance for the Content of Premarket Notifications for Urine Drainage Bags	5	6/ 7/94
097	Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley	11	9/12/94
	Catheters	11	
	Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology	5	11/ 1/94
099	Draft - 510(k) Checklist for Conditioned Response Enuresis Alarms	3	11/23/9
100	Draft Guidance Outline - Points to Consider for Clinical Studies for Vasovasostomy Devices	4	11/30/9
134	Gastroenterology and Urology Device Tier Designations	4	7/12/94
161	Draft Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary	7 38	5/ 1/95
1.60	Continence Device (Artificial Urinary Sphincter)	1.4	0/15/05
162	Draft Guidance for the Content of Premarket Notifications for Endoscopes Used in Gastroenterology	14	3/17/95
166	and Urology Draft Guidance for the Content of Premarket Notifications for Menstrual Tampons	28	5/25/95
177	Draft Guidance for the Content of Premarket Notifications for Penile Rigidity Implants	28 14	5/30/95
189	Draft 510(k) Checklist for Non-implanted Electrical Stimulators used for the treatment of Urinary	11	6/ 6/95
109	Incontinence	11	0/ 0/93
190	Draft 510(k) Checklist for Endoscopic Light Sources used in Gastroenterology and Urology	7	6/22/95
1907	Hysteroscopes & Gynecologic Laparoscopes: Submission Guidance for a 510(k)	23	3/27/96
192	SE Comparison Chart for Laparoscopes	6	5/25/95
202	Guidance to Manufacturers on the Development of Required Postapproval Epidemiologic Study	2	
	Protocols for Testicular Implants		
232		6	
	Guidance (Guidelines) for Evaluation of Fetal Clip Electrodes	4	3/8/77
	Guidance (Guidelines) for Evaluation of Tubal Occlusion Devices	7	11/22/7
248	Guidance (Guidelines) for Evaluation of Hysteroscopic Sterilization Devices	9	5/10/78
281	510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices	93	12/ 1/85
2907	510(k) Guidance for 2-D Laparoscope: SE Comparison Chart	7	10/10/9
323	Condom Labeling: To All U.S. Condom Manufacturers, Importers and Repackagers	5	4/ 7/87
327	Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochle		5/ 1/90
32,	Implant in Children Ages 2 through to 17 Years	. 2 .	5/ 1/70
335	Necessary Information for Diagnostic Ultrasound 510(k) - Draft	8	11/24/8
340	Guidance for Content and Review of a Magnetic Resonance Diagnostic Device 510(k) Application	122	8/ 2/88
358	Doppler Ultrasound Instrumentation; FDA 510(k) Guidance for the Preclinical Demonstration and	33	1/19/89
	Comparison of Effectiveness		
384	Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent	16	4/4/90
	Sexually Transmitted Disease		
3907	Hysteroscopic and Laparoscopic Insufflators: Submission Guidance for a 510(k)	20	10/10/9

		INGLO	<u>DITTE</u>
398	Condom Package	44	4/13/95
416	Guidance for the Comment and Review of 510(k) Notification for Picture Archiving and	9	8/ 1/93
	Communications Systems		
418	Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock	14	1/18/91
	Wave		
421	Guidelines for Premarket Testing of New Conventional Hemodialyzers, High Permeability	16	3/ 1/82
	Hemodialyzers and Hemofilters		
431	Guidance for the Content of Premarket Notifications for Ureteral Stents	6	2/10/93
455	Testing Guidance for Male Condoms Made from New Material (Non-Latex)	14	6/29/95
464	Guidance for Submission of a 510(k) for an Air Conduction Hearing Aid	11	4/ 1/91
482	Guidance for the Content of Premarket Notifications for Biopsy Devices used in Gastroenterology	8	2/10/93
	and Urology		
490	Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems	10	7/29/94
515	Draft 510(k) Checklist for Urological Irrigation System and Tubing Set	7	8/ 1/95
533	Draft Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic	16	11/11/9
	Hyperplasia (BPH)		
547	Draft Thermal Endometrial Ablation Devices: Submission Guidance for an IDE	22	3/14/96
567	Draft Guidance for the Content of Premarket Notification for Urological Balloon Dilation Catheters	11	1/24/92
577	Guideline for the Arrangement and Content of a Premarket Approval (PMA) Application for a	26	5/ 1/90
	Cochlear Implant in Adults at Least 18 Years of Age		
621	Premarket Testing Guidelines for Falloposcopes	12	11/20/9
634	Diagnostic Ultrasound 510(k) Guidance	63	2/17/93
641	Guidelines for Evaluation of Non-Drug IUDs	16	9/28/76
657	Cover Letter/Draft Guidance to Hearing Aid Manufacturers for Substantiation of Claims	11	8/ 5/94
667	Draft Guidance for the Preparation of a Premarket Notification for Extended Laparoscopy Devices	4	8/30/94
	(ELD)		
768	Draft 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in	7	8/16/95
	Gastroenterology and Urology		
788	Reviewer Guidance for Automatic X-Ray Film Processor 510(k)	2	2/ 1/90
791	Guidance for the Technical Content of a Premarket Approval (PMA) Application for an	3	4/ 1/90
	Endolymphatic Shunt Tube with Valve		
809	Draft Guidance for Preparation of PMA Application for Testicular Prostheses	51	3/16/93
810	Draft Guidance for Preparation of PMA Applications for Penile Inflatable Implants	55	3/16/93
820	Premarket Testing Guidelines for Home Uterine Activity Monitors	50	3/31/93
842	Draft Guidance for the Content of Premarket Notifications for Water Purification Components and	11	4/13/95
	Systems for Hemodialysis		
850	Draft Guidance for Preclinical and Clinical Investigations of Urethral Bulking Agents Used in the	21	11/29/9
	Treatment of Urinary Incontinence		
864	Draft Guidance for Information on Clinical Safety and Effectiveness Data for Extracorporeal Shock	13	2/ 5/92
	Wave Lithotripsy of Upper Urinary Tract (Renal Pelvis, Renal Calyx and Upper Ureteral) Calculi		
866	Draft Guidance for Review of Bone Densitometer 510(k) Submissions	23	11/9/92
892	Draft 510(k) Checklist for Sterile Lubricating Jelly Used with Transurethral Surgical Instruments	3	9/19/94
899	Letter/Guidance/Appendix on Hemodialyzer Reuse LabelingH	43	10/6/95
928	DRAERD Tier Categorizations; Triage Lists (includes 931)	14	1/27/94
932	DRAERD Triage Pilot Program, Description	13	12/15/9
966	Letter/Guidance for the Clinical Investigation of General Use Lasers Used Specifically for the	6	9/25/95
	Treatment of Benign Prostatic Hyperplasia (BPH)		

		INGLO	DITTE
	510(k) Checklist for Condom Catheters	3	2/23/95
992	Draft Guidance for the Content of Premarket Notifications for External Penile Rigidity Devices	14	3/21/95
ODE/O	THER\ GUIDANCE		
	An Introduction to Transcutaneous Electrical Nerve Stimulation: TENS	51	8/ 1/86
016	A Small Business Guide to FDA	12	1/ 1/87
023	Impact Resistant Lenses: Questions and Answers (Including Certification Statement)	18	9/ 1/87
	Five Videos on Hemodialysis	2	11/17/9
078	Perspectives on Clinical Studies for Medical Device Submissions (Statistical)	10	
084	PMA Review Statistical Checklist	2	
147	Premarket Submission Cover Sheet: Instructions, and Survery	18	1/19/95
150	Information on FDA's Proposed Pilot of Third Party Review of Medical Device 510(k)s)	19	5/26/95
198	Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer	29	4/26/96
	Guidance		
	Charts for: Design Control for Medical Device Manufacture (pages 7,9 & 10)	3	3/ 5/96
	Graphs for Do It By Design - An Introduction to Human Factors in Medical Devices	11	3/ 6/96
223	Latex Bibliography	3	3/22/91
225	Methods for Conducting Recall Effectiveness Checks	10	6/16/78
226	Medical Device Reporting (MDR)	2	9/ 8/95
227	Human Factors Principles for Medical Device Labeling	37	9/ 1/93
228	Suggestions for Submitting Premarket Approval (PMA) Application	2	4/ 1/93
2337	510(k) Software Documentation Matrix; Page 16 of the Reviewer Guidance for Computer Controlled	. 1	8/29/91
226	Devices Undergoing 510(k) Review	~	0/1/07
236	Abbreviated Reports on Radiation Safety for Microwave Product (Other than Microwave Ovens)	5	8/ 1/95
	E.G. Microwave Heating, Microwave Diathermy, RF Sealers, Induction, Dielectric Heaters, Security		
247	Systems Application of the Medical Davies CMPs to Computarized Davies and Manufacturing Processes	27	2/21/96
247	Application of the Medical Device GMPs to Computerized Devices and ManufacturingProcesses Medical Device Guidance for FDA Investigators	21	2/21/90
267	Application of the Device Good Manfuacturing Practice (GMP) Reguation to the Manufacture of	14	12/ 1/83
207	Sterile Device	14	12/ 1/03
268	Color Additive Status List (Inspection Operations Manual)	10	2/ 1/89
	Points to Consider in the Characterization of Cell Line Used to Produce Biological Products	64	6/ 1/84
	Electrical Muscle Stimulator (EMS) Labeling Indications; Contraindications; Warnings; etc.	2	7/11/85
	FDA Guide for Validation of Biological Indicator Incubation Time	4	1/ 1/86
284	Biotechnology and FDA Regulation of Hybridoma In Vitro Diagnostic Products: List of Current	4	1/ 1/86
	Devices and Guidelines for Manufacturers		
286	Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for	24	3/ 1/88
	Microwave Ovens Compliance Survery Instruments		
287	Guidance on Significant and Nonsignificant Risk Device Studies	10	10/ 1/95
288	FDA Clinical Investigator Information Sheets	54	5/ 1/89
295	Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers	25	9/ 1/89
	FDA 90-4236		
296	Color Additive Petitions	2	6/ 1/87
298	Office of Device Evaluation (ODE) Guidance Documents FY86 - FY87	6	10/ 1/87
311	Suggested Format for IDE Progress Reports	1	
329	Industry Representative on Scientific Panels	4	3/27/87
337	Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review	43	8/29/91

		IAGES	DATE
338	Master Files: Part III; Guidance on Scientific and Technical Information	7	6/ 1/87
351	FDA Policy for the Regulation of Computer Products	3	11/13/8
352	Threshold Assessment of the Impact of Requirements for Submission of PMAs for 31 Medical	8	1/ 1/90
	Devices Marketed Prior to May 28, 1976		
359	Directory of Companies Performing Primary Skin Irritation and Human Dermal Toxicity Testing	10	2/15/94
363	Toxicology Risk Assessment Committee	4	8/9/89
367	Meetings with the Regulated Industry (#I89-3)	3	11/20/8
371	4-Of-a-Kind PMAs	2	10/ 1/91
390	Substantial Equivalence (SE) Decision Making Documentation	5	1/ 1/90
415	Shelf life of Medical Devices	26	3/ 1/91
420	Product Development Protocol Guideline (PDP)	22	11/1/80
423	Guideline for Preparing Notices of Availability of Investigational Medical Devices	4	11/ 1/85
425	Guideline on General Principles of Process Validation	13	5/ 1/87
426	Guideline on Sterile Drug Products Produced by Aseptic Processing	44	6/ 1/87
427	Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-product Test for	44	12/ 1/87
400	Human and Animal Parenteral Drugs, Biological Products and Medical Devices		4 / 4 /00
428	Guideline for the Monitoring of Clinical Investigations	9	1/ 1/88
448	Guidance for Prepartion of PMA Manufacturing Information	12	8/ 1/92
476	Clinical Trial Guidance for Non-Diagnostic Medical Devices	36	1/ 1/96
487	Premarket Notification Certification and Summary (to be submitted when claiming equivalence to a	1	1/14/91
401	Class III device)	_	2/11/00
491	Condoms for Prevention of Sexually Transmitted Diseases	5	3/11/88
497	Guidance to Manufacturers on the Development of Required Postmarket Surveillance Study Protocols	s 14	11/8/91
521	Under Section 522 (a)(1) of the Federal Food, Drug and Cosmetic Act	12	10/31/9
521	Intercenter Agreement Between The Center for Biologics Evaluation and Research and The Center for Davises and Rediclogical Health	r 12	10/31/9
524	Devices and Radiological Health Intercenter Agreement Between The Center for Drug Evaluation and Research and The Center for	14	10/31/9
324	Devices and Radiological Health	14	10/31/9
537	Statistical Aspects of Submissions to FDA: A Medical Device Perspective	20	6/ 1/84
575	Color Additive for Medical Devices	26	11/15/9
584		13	3/11/92
	Premarket Notification Truthful and Accurate Statement (As Required by 21 CFR 807.87(j))	3	3/14/95
	Premarket Notification Class III Certification and Summary (As Required by 21 CFR 807.94)	2	3/14/95
598	Premarket Notification 510(k) Statement (As Required by 21 CFR 807.93)	2	3/14/95
607	Device, Drug or Cosmetic	27	8/26/91
609	Guidance for Submitting Reclassification Petition	11	
613	Automatic Detention of Medical Devices	6	3/ 7/94
671	List of Contract Sterilizers	5	9/ 1/89
789	Classified Convenience Kits	3	11/19/9
797	Suggested Content for Original IDE Application Cover Letter	1	2/27/96
806	Radiation Exposure from Medical Imaging Demonstrations	3	5/10/90
814	Certified Color Manufacturers - List of Manufacturers Names and Addresses From 1990 to Present	4	12/3/92
815	Device Specific Guidance Documents	8	5/11/93
829	Biocompatibility of Medical Devices	25	4/15/93
858	Premarket Notification [510(k)] Status Request Form	1	12/20/9
879	Indication for Use Statement / Change in 510(k) Format	2	4/24/96
891	Medical Device Clinical Study Guidance	48	9/21/93

	DSMA Facts Domain		
		<u>PAGES</u>	DATE
912	Addendum: How to Submit a Premarket Notification [510(k)] Data	16	3/ 1/95
935	Deciding When to Submit a 510(k) for Change to an Existing Device (includes 936)	37	8/ 1/95
936	Attachments to #935: Deciding When to Submit (included with 935)	5	8/ 1/94
937	Premarket Approval Applications; Most Recent Monthly Update	7	5/22/96
939	Medical Device Exemptions List	14	7/18/95
944	Testing for Skin Sensitization to Chemicals in Latex Products - Proposed Modified Guidance	6	8/28/95
964	Coronary and Cerebrovascular Guidewire Guidance	3	1/ 1/95
994	Design Control Guidance for Medical Device Manufacturers	1	3/29/96
995	Do It By Design - An Introduction to Human Factors in Medical Devices	1	3/29/96
OTHEI	RINSTRUCTIONS		
294	RAPS Electronic Media Services/RAPS Fax-on-Demand Hotliine	1	2/21/96
520	How to Make A Freedom of Information (FOI) Act Request to FDA	1	11/1/91
POSTM	AARKET SURVEILLANCE\OTHER		
	Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for	16	6/ 6/93
	Permanent Implantable Cardiac Pacemaker Electrodes (Leads)		
341	FDA/CPSC Public Health Advisory: Hazards Associated with the Use of Electric Heating Pads	3	12/12/9
	Medical Device Notification and Voluntary Safety Alert Guideline	13	3/ 1/84
463	FDA Medical Alert - Allergic Reactions to Latex-Containing Medical Devices	2	3/29/91
PUBLI	C INFORMATION\OTHER		
429	Important Information on Shiley C-C Valve Fractures	4	4/21/92
438	Condoms and Sexually Transmitted Diseases Especially AIDS	8	1/ 1/90
439	Visitors Guide to CDRH Buildings/Twinbrook, Chapman, Wilkins, Piccard	4	1/ 1/90
440	AIDS - Information for the Dialysis Health Professional	4	1/ 1/90
441	AIDS - Information for the Dialysis Patient	4	1/ 1/90
442	It's Not Only A Good Idea - It's Also The Law	2	4/4/04
488	FDA Consumer Magazine: Contact Lenses: The Better the Care the Safer the Wear	4	4/ 1/91
504	Medications that Increase Sensitivity to Light: 1 1990 Listing	24	12/ 1/90
	FDA Consumer Magazine: Healthy Tan' - A Fast Fading Myth	4	6/ 1/89
541	HHS News Release on Breast Implants with Attachments - Statement on Silicone Gel Breast	10	1/6/91
	Implants, FDA Medical Alert: FDA Request Moratorium on Silicone Breast Implants, FDA Backgrounder: Important Information on Breast Implants		
561	FDA Consumer: EMS Fraudulent Flab Remover	4	5/ 1/83
569	FDA Consumer: Do-It-Yourself Medical Testing	8	2/ 1/86
572	FDA Consumer: A Complaint Department for Medical Devices	4	3/ 1/87
573	FDA Consumer: Are Your Contact Lenses as Safe as You Think?	4	4/ 1/87
578	FDA Consumer: The Medical Device Amendments: 10 Years After	4	5/ 1/86
579	Yorick The CDRH Bionic Skeleton	2	1/ 1/89
581	FDA Consumer: A Primer on Medical Imaging - Part One	8	4/ 1/89
590	Update on Possible Hazards of Traffic Radar Devices	2	7/20/92
643	Information for Women Considering Saline-Filled Breast Implants	4	4/20/95
942	FDA Fact Sheet Mammography Quality Standard Act	1	9/28/94

RADIOLOGICAL HEALTH - LASERS

230 Letter to Manufacturers and Importers: Lasers and Laser Products 251 Reporting Guide for Laser Light Shows and Displays (21 CFR 1002) FDA 95-8140 262 Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show 263 Products 277 Guide for Preparing Product Reports for Lasers and Products Containing Lasers 278 Viable Bacteriophage in CO2 Laser Plume: Aerodynamic Size Distribution 279 Sylable Bacteriophage in CO2 Laser Plume: Aerodynamic Size Distribution 280 Review of "YAG" Lasers for Neurosurgery 280 Guide for Preparing Reports on Radiation Safety of Microwave Ovens 280 Guide for Preparing Reports on Radiation Safety of Microwave Ovens 280 Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 281 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 281 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 282 2/175 282 ADDIOLOGICAL HEALTH - OTHER 283 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 284 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 285 Pablic Law 90-602 286 Public Law 90-602 287 ADDIOLOGICAL HEALTH - OTHER 280 Guida Reports Regulations for Radiation Emmitting Electronic Products 281 Letter: All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA 285 Performance Standards Exist 286 Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps 287 and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 288 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 289 Letter to Manufacturers and Importers Sunlamp Products 290 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 291 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 292 Guide for Preparing Annual Reports and Model Change Repor		DSMA Facts Domain	PAGES	DATE
25 Reporting Guide for Laser Light Shows and Displays (21 CFR 1002) FDA 95-8140 22 9/195 700				
25 Reporting Guide for Laser Light Shows and Displays (21 CFR 1002) FDA 95-8140 22 9/1/95 700 70	230	Letter to Manufacturers and Importers: Lasers and Laser Products	6	9/14/95
29 1/95		-	22	9/ 1/95
271 Guide for Preparing Product Reports for Lasers and Products Containing Lasers 19 195 195 195 195 195 196	264		12	9/ 1/95
Section Sect		Products		
RADIOLOGICAL HEALTH - MICROWAVE 239 Guide for Preparing Reports on Radiation Safety of Microwave Ovens RADIOLOGICAL HEALTH - NON-IONIZING 240 Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 1002.10 241 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 242 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 243 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 244 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 255 PADIOLOGICAL HEALTH - OTHER 266 1990 Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1909. 1909	277		33	9/ 1/95
RADIO LOGICAL HEALTH - MICROWAVE 239 Guide for Preparing Reports on Radiation Safety of Microwave Ovens RADIO LOGICAL HEALTH - NON-IONIZING 240 Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 1002.10 241 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 252 Zero Standards Experiment Administration of the Radiation Control for Health and Safety Act of 1990 Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968 Public Law 90-602 1040 Records and Reports Regulations for Radiation Emmitting Electronic Products 1968 Public Law 90-602 1140 Records and Reports Regulations for Radiation Emmitting Electronic Products 1970 Physics 1970		•	19	
RADIO-LOGICAL HEALTH - NON-IONIZING 240 Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 9 4/30/74 1002.10 241 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 242 Z/ 1/75 RADIO-LOGICAL HEALTH - OTHER 343 By On Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968 Public Law 90-602 144 Records and Reports Regulations for Radiation Emmitting Electronic Products 145 Performance Standards Exist 142 Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 244 Guide for Preparing Annual Reports on Radiation Safety Testing of Electroric Products (General) 245 Guide for Preparing Annual Reports on Radiation Safety Testing of Electroric Products (General) 246 Guide for Preparing Annual Reports on Radiation Safety Testing of Electroric Products (General) 257 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 258 RADIO-LOGICAL HEALTH - SUNLAMPS 259 Letter to Manufacturers and Imports: Sunlamp Porducts, Ultraviolet Lamps and Associated 250 Equipment 261 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 262 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 264 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 275 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 276 Guide for Preparing Initial Reports and Model Change Reports on High Intensity Mercury Vapor 277 Guide for Preparing Initial Reports and Model Change Reports on High Intensity Mercury Vapor 278 Discharge Lam	620	Review of "YAG" Lasers for Neurosurgery	1	
RADIO-LOGICAL HEALTH - NON-IONIZING 240 Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 9 4/30/74 1002.10 241 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 242 Z/ 1/75 RADIO-LOGICAL HEALTH - OTHER 343 By On Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968 Public Law 90-602 144 Records and Reports Regulations for Radiation Emmitting Electronic Products 145 Performance Standards Exist 142 Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 244 Guide for Preparing Annual Reports on Radiation Safety Testing of Electroric Products (General) 245 Guide for Preparing Annual Reports on Radiation Safety Testing of Electroric Products (General) 246 Guide for Preparing Annual Reports on Radiation Safety Testing of Electroric Products (General) 257 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 258 RADIO-LOGICAL HEALTH - SUNLAMPS 259 Letter to Manufacturers and Imports: Sunlamp Porducts, Ultraviolet Lamps and Associated 250 Equipment 261 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 262 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 264 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 275 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 276 Guide for Preparing Initial Reports and Model Change Reports on High Intensity Mercury Vapor 277 Guide for Preparing Initial Reports and Model Change Reports on High Intensity Mercury Vapor 278 Discharge Lam	RADIO	OLOGICAL HEALTH - MICROWAVE		
240 Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 1002.10 241 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 242 Z/ 1/75 RADIOLOGICAL HEALTH - OTHER 036 1990 Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968 Public Law 90-602 1040 Records and Reports Regulations for Radiation Emmitting Electronic Products Performance Standards Exist 242 Guide for Preparing Annual Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 244 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 254 Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer 255 Reducing Patient Exposure During Scoliosis Radiography 26 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 270 Quality Control Guide for Sunlamp Products 28 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 29 Letter to Manufacturers and Imports: Sunlamp Porducts, Ultraviolet Lamps and Associated 20 Guide for Preparing Initial Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 29 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 20 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 21 (CFR 1002) 23 Hopping Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor 23 11/16/9 24 Discharge Lamps 25 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; 10 Pyly5 11/29/9			67	3/ 1/85
240 Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 1020.40 24 1 Oudance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 28 2/ 1/75 RADIOLOGICAL HEALTH - OTHER 036 1990 Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968 Public Law 90-602 11968 Public Law 90-602 11969 Public Public Law 90-602 11969 Public Law 90-602 11969 Public Law 90-60	PADIO	I OCICAL HEALTH - NON IONIZING		
1002.10 241 Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40 25 2/ 1/75 RADIOLOGICAL HEALTH - OTHER 036 1990 Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1996 Public Law 90-602 1040 Records and Reports Regulations for Radiation Emmitting Electronic Products 25 Letter: All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA 15 5/28/81 Performance Standards Exist 242 Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 11 10/1/87 254 Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 8 9/1/95 263 Reducing Patient Exposure During Scoliosis Radiography 2 1/1/85 RADIOLOGICAL HEALTH - SUNLAMPS 229 Letter to Manufacturers and Imports: Sunlamp Porducts, Ultraviolet Lamps and Associated 1 9/14/95 270 Quality Control Guide for Sunlamp Products 2 10 9/1/95 271 Quality Control Guide for Sunlamp Products 2 10 9/1/95 272 Quality Control Guide for Sunlamp Products 2 10 9/1/95 273 Quality Control Guide for Sunlamp Products 2 10 9/1/95 274 Quality Control Guide for Sunlamp Annual Reports and Model Change Reports on Sunlamps and Sunlamp Products 2 10 9/1/95 272 Quality Control Guide for Sunlamp Products 2 10 9/1/95 273 Patient Sunlamp Products 2 10 9/1/95 274 Quality Control Guide for Sunlamp Reports and Model Change Reports on High Intensity Mercury Vapor 2 11/1/6/9 275 Patient Sunlamp Products 1 11/16/9 276 Patient Sunlamp Products 2 10 1/1/6/9 277 Patient Sunlamp Products 2 10 1/1/6/9 278 Patient Sunlamp Products 1 1/1/6/9 279 Patient Sunlamp Products 1 1/1/6/9 280 Patient Sunlamp Products 1 1/1/6/9 281 Patient Sunlamp Product			Q	4/30/74
RADIOLOGICAL HEALTH - OTHER 036 1990 Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968 Public Law 90-602 1040 Records and Reports Regulations for Radiation Emmitting Electronic Products 17 9/19/95 231 Letter: All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA 15 5/28/81 Performance Standards Exist 18 242 Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps 17 4/1/89 and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 11 10/1/87 254 Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer 10 11/1/80 Equipment Pursuant to 21 CFR 1002.10 and 1002.12 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 8 9/1/95 366 Reducing Patient Exposure During Scoliosis Radiography 2 1/1/85 RADIOLOGICAL HEALTH - SUNLAMPS 229 Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment 2 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 3 3/1/88 279 Quality Control Guide for Sunlamp Products 2 79 1/95 210 Quality Control Guide for Sunlamp Products 2 79 9/1/95 210 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 2 79 9/1/95 2 1/	240			4/30/74
1990 Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968 Public Law 90-602 1040 Records and Reports Regulations for Radiation Emmitting Electronic Products 17 9/19/95 231 Letter: All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA 15 5/28/81 Performance Standards Exist 15 242 Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 11 10/187 254 Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 8 9/1/95 566 Reducing Patient Exposure During Scoliosis Radiography 8 9/1/95 265 Reducing Patient Exposure During Scoliosis Radiography 8 2 1/1/85 RADIOLOGICAL HEALTH - SUNLAMPS 229 Letter to Manufacturers and Imports: Sunlamp Porducts, Ultraviolet Lamps and Associated 1 9/14/95 260 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 36 3/1/88 279 Quality Control Guide for Sunlamp Products 36 3/1/88 279 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 27 9/1/95 21 CFR 1002) 348 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor 23 11/16/9 Discharge Lamps RADIOLOGICAL HEALTH - TELEVISION 259 T.V. Standards Information for: Television Receivers / Products with Liquid Crystal Displays; 29 8/25/94 Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated	241	Guidance for the Submission of Cabinent X-Ray System Reports Pursuant to 21 CFR 1020.40	28	2/ 1/75
1990 Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968 Public Law 90-602 1040 Records and Reports Regulations for Radiation Emmitting Electronic Products 17 9/19/95 231 Letter: All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA 15 5/28/81 Performance Standards Exist 15 242 Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 11 10/187 254 Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 8 9/1/95 566 Reducing Patient Exposure During Scoliosis Radiography 8 9/1/95 264 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 10 9/14/95 275 Equipment 10 9/14/95 286 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 10 9/14/95 287 Quality Control Guide for Sunlamp Products 10 9/14/95 288 Quality Control Guide for Sunlamp Products 10 9/14/95 299 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 10 9/14/95 201 CFR 1002) 348 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor 10 11/16/9 11/16/9 Discharge Lamps 298 RADIOLOGICAL HEALTH - TELEVISION 2 9/14/95 299 T.V. Standards Information for: Television Receivers / Products with Liquid Crystal Displays; 29/14/95 11/16/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 11/29/9 1002.10) Supplemental Report (21 CFR 1002.	RADIO	OLOGICAL HEALTH - OTHER		
1968 Public Law 90-602 1040 Records and Reports Regulations for Radiation Emmitting Electronic Products 21 Letter: All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA 15 5/28/81 Performance Standards Exist 242 Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 11 10/1/87 254 Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 8 9/1/95 263 Reducing Patient Exposure During Scoliosis Radiography 2 1/1/85 RADIOLOGICAL HEALTH - SUNLAMPS 229 Letter to Manufacturers and Imports: Sunlamp Porducts, Ultraviolet Lamps and Associated Equipment Equipment 20 2 2 1/1/85 RADIOLOGICAL HEALTH - SUNLAMPS 229 Cuide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 10 9/1/95 270 Quality Control Guide for Sunlamp Products 27 Quality Control Guide for Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 27 9/1/95 (21 CFR 1002) 348 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor 23 11/16/9 Discharge Lamps RADIOLOGICAL HEALTH - TELEVISION 259 T.V. Standards Information for: Televisions/Exempt. from Reporting/Recordkeeping 260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR			71	4/ 1/91
Letter: All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA Performance Standards Exist 242 Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 254 Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 8 9/1/95 266 Reducing Patient Exposure During Scoliosis Radiography 27 1/85 RADIOLOGICAL HEALTH - SUNLAMPS 28 Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment 262 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 264 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 27 9/1/95 270 Quality Control Guide for Sunlamp Products 270 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 27 9/1/95 28 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor 28 Discharge Lamps RADIOLOGICAL HEALTH - TELEVISION 29 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; 29 8/25/94 260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Repo	030		, 1	4/ 1//1
Performance Standards Exist 242 Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 11 10/1/87 254 Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer 10 11/1/80 Equipment Pursuant to 21 CFR 1002.10 and 1002.12 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 8 9/1/95 266 Reducing Patient Exposure During Scoliosis Radiography 2 1/1/85 RADIOLOGICAL HEALTH - SUNLAMPS 229 Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment 262 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 36 3/1/88 279 Guide for Preparing Initial Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 36 3/1/88 279 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 27 9/1/95 (21 CFR 1002) 348 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps RADIOLOGICAL HEALTH - TELEVISION 259 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; 29 8/25/94 Import. of Noncompl. Television/Exempt. from Reporting/Recordkeeping 260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 1002			17	9/19/95
242 Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 244 Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 245 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 246 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 257 RADIOLOGICAL HEALTH - SUNLAMPS 258 Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment 269 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 260 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 270 Quality Control Guide for Sunlamp Products 271 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 272 9/1/95 273 Guide for Preparing Initial Reports and Model Change Reports on High Intensity Mercury Vapor 273 11/16/9 274 Discharge Lamps 275 RADIOLOGICAL HEALTH - TELEVISION 276 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; 277 Inport. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 288 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 1002.10)	231	*	15	5/28/81
and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12) 243 Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 254 Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer 255 Equipment Pursuant to 21 CFR 1002.10 and 1002.12 266 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 256 Reducing Patient Exposure During Scoliosis Radiography 257 RADIOLOGICAL HEALTH - SUNLAMPS 268 Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated 279 Equipment 269 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 270 Quality Control Guide for Sunlamp Products 271 Oquality Control Guide for Sunlamp Products 272 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 270 Guide for Preparing Initial Reports and Model Change Reports on High Intensity Mercury Vapor 270 Discharge Lamps 271 Products 272 Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor 273 Discharge Lamps 274 Products 275 Fr.V. Standards Information for: Television Receivers / Products with Liquid Crystal Displays; 276 Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 277 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 1002.11)				
Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps Radio Frequency Dielectric Heater and Sealer Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps Radio LOGICAL HEALTH - SUNLAMPS Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products Guide for Preparing Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps RADIO LOGICAL HEALTH - TELEVISION 259 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR	242		17	4/ 1/89
Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 8 9/ 1/95 566 Reducing Patient Exposure During Scoliosis Radiography 2 1/ 1/85 RADIOLOGICAL HEALTH - SUNLAMPS 229 Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment 262 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 10 9/ 1/95 270 Quality Control Guide for Sunlamp Products 36 3/ 1/88 279 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products (21 CFR 1002) 348 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps RADIOLOGICAL HEALTH - TELEVISION 259 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; 29 8/25/94 Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 11/29/9 1002.10)	2.42		1.1	10/1/07
Equipment Pursuant to 21 CFR 1002.10 and 1002.12 263 Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 566 Reducing Patient Exposure During Scoliosis Radiography 2 1/1/85 RADIOLOGICAL HEALTH - SUNLAMPS 229 Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment 262 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 270 Quality Control Guide for Sunlamp Products 270 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 270 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 280 (21 CFR 1002) 281 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps RADIOLOGICAL HEALTH - TELEVISION 282 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 283 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 11/29/9)				
Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps RADIOLOGICAL HEALTH - SUNLAMPS 229 Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment 260 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 270 Quality Control Guide for Sunlamp Products 270 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 270 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 270 Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor 280 Discharge Lamps RADIOLOGICAL HEALTH - TELEVISION 29 8/25/94 Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 29 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 70 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR	254		10	11/ 1/80
RADIOLOGICAL HEALTH - SUNLAMPS 229 Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment 260 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 270 Quality Control Guide for Sunlamp Products 270 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 270 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 270 Guide for Preparing Initial Reports and Model Change Reports on High Intensity Mercury Vapor 281 C1 CFR 1002) 382 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor 383 Discharge Lamps 284 Discharge Lamps RADIOLOGICAL HEALTH - TELEVISION 285 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; 29 8/25/94 Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 286 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 11/29/9 1002.10)	263	• •	Q	0/ 1/05
RADIOLOGICAL HEALTH - SUNLAMPS 229 Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment 262 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 270 Quality Control Guide for Sunlamp Products 280 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 280 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 280 (21 CFR 1002) 381 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps 282 BADIOLOGICAL HEALTH - TELEVISION 283 T.V. Standards Information for: Television Receivers / Products with Liquid Crystal Displays; 184 Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 285 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 298 8/25/94 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR				
229 Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment 262 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 270 Quality Control Guide for Sunlamp Products 270 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 270 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 270 (21 CFR 1002) 281 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps 282 Products with Liquid Crystal Displays; 283 Products With Liquid Crystal Displays; 294 Products With Liquid Crystal Displays; 295 Products With Liquid Crystal Displays; 296 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 11/29/9 1002.10)	300	Reducing I attent Exposure During Sconosis Radiography	2	1/ 1/03
Equipment 262 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 270 Quality Control Guide for Sunlamp Products 271 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products 272 9/ 1/95 (21 CFR 1002) 348 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps 259 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR	RADIO	LOGICAL HEALTH - SUNLAMPS		
 Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products Quality Control Guide for Sunlamp Products	229		1	9/14/95
270 Quality Control Guide for Sunlamp Products 272 Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products (21 CFR 1002) 348 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps RADIOLOGICAL HEALTH - TELEVISION 259 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR	2.62	• •	10	0/1/07
27 9/ 1/95 (21 CFR 1002) 348 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps 27 9/ 1/95 (21 CFR 1002) 348 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps 28 11/16/9 29 8/25/94 Import. of Noncompl. Television Receivers / Products with Liquid Crystal Displays; Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR				
(21 CFR 1002) 348 Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps RADIOLOGICAL HEALTH - TELEVISION 259 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR				
RADIOLOGICAL HEALTH - TELEVISION 23 11/16/9 24 11/16/9 25 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; Limport. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 26 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR)	219		21	9/ 1/95
RADIOLOGICAL HEALTH - TELEVISION 259 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; 29 8/25/94 Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR	348		23	11/16/9
 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 		Discharge Lamps		
 T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR 	RADIO	DLOGICAL HEALTH - TELEVISION		
Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping 260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR			29	8/25/94
260 Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 71 11/29/9 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report (21 CFR				
	260		71	11/29/9
1002.12) Annual Report (21 CFR 1002.13) Information and Guidance				
		1002.12) Annual Report (21 CFR 1002.13) Information and Guidance		

	DSMA Facts Domain	PAGES	DATE
		IAGES	DAIL
RADIO	LOGICAL HEALTH - ULTRASONIC		
	Abbreviated Reports on Safety of Non-Medical Ultrasonic Products	5	8/ 1/95
	· · · · · · · · · · · · · · · · · · ·		
	ATIONS\CFR PARTS		
	21 CFR Part 50, et al. Protection of Human Subjects; Informed Consent; Proposed Rule	19	9/21/95
1336	Federal Register: Extension of Effective Date: Medical Device; Medical Device User Facility and Manufacturer Reporting, Certification and Registration; Office of Managment and Budget Approval;	3	4/11/96
	Final rule		
	ATIONS\FOREIGN The Medical Device Amendments of 1076, as Eurther Amended by the Sefe Medical Devices Act of	41	1/ 1/95
000	The Medical Device Amendments of 1976, as Further Amended by the Safe Medical Devices Act of 1990	41	1/ 1/93
018	An Introduction to Medical Device Regulations	6	
027	House of Representatives Report 101-808 Safe Medical Devices Act of 1990	81	10/5/90
029	Device User Facility Reporting Sections of the Safe Medical Devices Act of 1990 (Public Law	7	
102	101-629) Reinventing Drug & Medical Davies Regulations	27	4/ 1/95
	Reinventing Drug & Medical Device Regulations Proposed Regulatory Requirements for Medical Devices Sold in Canada	37 126	1/26/96
	FDA IRB Information Sheet	107	1/20/50
332	Citizen Petition - Points to Consider	10	5/ 5/94
	30-Point Summary; Medical Device Amendments of 1976 (Publica Law 94-295)	2	1/ 1/76
	Need Help With Medical Device Regulations? Contact DSMA	2	1/ 1/95
	Public Law 102-539 Mamography Quality Standards Act of 1992	16	10/27/9
610	U.S. Food and Drug Administration Regulation of Medical Devices (Background Information for Foreign Officials)	52	12/ 1/95
REGUL	ATIONS\OTHER		
	List of Eligible Devices	30	4/ 3/96
	Comparison of Drug and Device Good Manufacturing Practice Regulations	16	1/ 1/81
411	Suggested Changes to the Medical Device Good Manufacturing Practices Regulation Petition Guidelines on Exemption or Variance from the Device GMP Regulation	30 7	11/ 1/90 9/ 1/79
417	Tethon Guidennes on Exemption of Variance from the Device Givil Regulation	,	9/ 1/19
REGUL	ATIONS\UNCODIFIED		
	Safe Medical Devices Act of 1990, PL 101-629	21	11/28/9
1030	Proposed Reclassification & Exemption from Premarket Notification of Certain Medical Devices;	84	7/28/95
1021	Docket 95N-0139 21 CER Parts 862 and 872 Madical Davisass Examption from Promorbat Natification for Contain	15	7/29/05
1031	21 CFR Parts 862 and 872 - Medical Devices; Exemption from Premarket Notification for Certain Classified Medical Devices; Final Rule Docket 94M-0260	15	7/28/95
1032	21 CFR Part 866 - Immunology and Microbiology Devices: Revocation of the Exemption from	10	7/28/95
	Premarket Notification; Blood Culturing System Devices; Final Rule Docket 91N-0063		
1033	21 CFR Part 862, 864, 866, 868, and 886 - Medical Devices; Withdrawal of Proposed Exemptions;	6	7/28/95
	Proposed Rule; Withdrawal; Docket 94M-0260		4/0/2
	FR Notice: Third Party Review of Selected Premarket Notification; Pilot Program FP Notice of Availability, Working Profit of the Current Gold Manufacturing Practice (CGMP) Finel	9 I 7	4/ 3/96 7/ 1/95
1303	FR Notice of Availability, Working Draft of the Current Godd Manufacturing Practice (CGMP) Final Rule; July 1995	ı /	1/ 1/93
	,y//-		

	Donari i ucas Donium	PAGES	DATE
		111020	
2258	Third Party review of Selected Premarket Notifications [510(k)s]	2	4/ 1/96
2303	Preamble - Working Draft of the Current GMP Final Rule July 1995	89	7/ 1/95
3303	Regulation - Working Draft of the Current GMP Final Rule July 1995	19	7/31/95
SAFET	Y ALERTS		
068	FDA Public Health Advisory: Avoiding Injuries from Rapid Drug or I.V. Fluid Administration Associated with I.V. Pumps and Rate Controller Devices	3	3/ 1/94
081	FDA Public Health Advisory: Retinal Photic Injuries From Operating Microscopes During Cataract Surgery	4	10/16/9
218	FDA Safety Alert: For Salt Tablet Users	1	1/ 1/89
219	FDA Safety Alert: Important Tips for Apnea Monitor Users	4	2/16/90
220	FDA Safety Alert: Gas/Air Embolism Associated with Intrauterine Laser Surgery	2	5/11/90
221	FDA Safety Alert: Serious Problems with Proplast - Coated TMJ Implant	2	12/28/9
222	FDA Safety Alert: Hepatitis B Transmission Via Spring-Loaded Lancet Devices	2	8/28/90
549	FDA Safety Alert: Aluminum and Other Trace Element Contamination in Dialysis Facilities	2	5/20/92
860	FDA Safety Alert: Entrapment Hazards with Hospital Bed Side Rails	4	8/23/95
VIDEO	& TELECONFERENCES		
975	Information Session for Prospective Third Parties	42	4/15/96

	DOI SA Pacts Domain	PAGES	S DATE
ANEST 03001	HESIA & RESPIRATORY (PULMONARY) Anesthesia Apparatus Checkout Recommendations, 1993	1	10/24/9
GASTR 07001	OENTEROLOGY & UROLOGY DEVICES Order Form: Five Videos on Hemodialysis	2	11/17/9
HOME	USE DEVICES		
20001	Medical Devices Used in Home Health Care FDA 92-4252. 1992	42	10/26/9
HUMA	N FACTORS & INSTRUCTIONS FOR USE		
02201	Human Factors Principles for Medical Device Labeling. 1993	37	10/24/9
02202	Write It Right. 1993	68	10/24/9
02203	FDA's Goals: Improved Medical Device Design	6	6/13/96
RADIO	LOGICAL DEVICES (NON-IONIZING)		
17001	Radio Waves May Interfere with Control of Powered Wheelchair. 1994	5	10/24/9
USER F	ACILITY REPORTING UNDER SMDA		
01001	User Facility Bulletin (Issue 01 Summer 1992)	6	10/24/9
01002	User Facility Bulletin (Issue 02 Fall 1992)	8	10/24/9
01003	User Facility Bulletin (Issue 03 Winter 1992)	6	10/24/9
01004	User Facility Bulletin (Issue 04 Spring 1993)	8	10/24/9
01005	User Facility Bulletin (Issue 05 Summer 1993)	8	10/24/9
01006	User Facility Bulletin (Issue 06 Fall 1993)	8	10/24/9
01007	User Facility Bulletin (Issue 07 Winter 1993)	4	10/24/9
01008	User Facility Bulletin (Issue 08 Spring 1994)	6	10/24/9
01009	User Facility Bulletin (Issue 09 Summer 1994)	6	10/24/9
01010	User Facility Bulletin (Issue 10 Fall/Winter 1994)	8	5/26/95
01011	User Facility Bulletin (Issue 11 Spring 1995)	8	10/24/9
01012	User Facility Bulletin (Issue 12 Summer 1995)	4	2/9/96
01035	Medical Device Tracking: Questions and Answers on Final Rule. 1992	40	10/24/9

		PAGES	DATE
MOSA	DOCUMENTS		
_			
002	MQSA of 1992	39	5/26/9
003	Mammography Quality Standards Act of 1992, FR	4	7/ 7/95
004	Mammography Matters Winter/Spring 1995	12	7/13/9
005	Mammography Matters; Fall 1994	12	7/13/9
006	Mammography Matters; Summer 1994	12	7/13/9
007	Mammography Matters; Spring 1994	8	7/13/9
800	Mammography Matters; Winter 1994	8	7/13/9